

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Jane Hirsh, Roman V. Rariy, Shubha Chungi, Michael Heffernan and  
Srinivas G. Rao

Serial No.: 10/690,947

Art Unit: 1615

Filed: October 22, 2003

Examiner: Humera N. Sheikh

For: *MODIFIED RELEASE COMPOSITIONS OF MILNACIPRAN*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R. § 1.132**

The undersigned, Dr. Martin Keller, does hereby declare and state that:

1. I am the Mary E. Zucker Professor and Chairman of the Department of Psychiatry and Human Behavior at Brown Medical School in Providence, RI, as well as Psychiatrist-in-Chief at Butler Hospital and Executive Psychiatrist-in-Chief at the six Brown Medical School affiliated hospitals. I have received more than 20 research grant awards from the NIH and numerous grants from research foundations and the pharmaceutical industry. I am the recipient of the 1998 National Alliance for Research on Schizophrenia and Depression (NARSAD) Lieber award for research on the causes, pathophysiology, treatment, and prevention of depression. I was awarded the 1999 Klerman Lifetime Research Award from the National Depression and Manic Depression Association. I was also the recipient of the 2001 American College of Psychiatrists

Mood Disorders Lifetime Research Award for major research contributions to the understanding and treatment of mood disorders and 2005 Voice of Mental Health Award from The Jed Foundation for contributions in the area of suicide prevention. My CV is attached as Appendix A.

2. This application is assigned to Collegium Pharmaceutical. I have not been paid to render this opinion nor am I an inventor or direct beneficiary of this application.

However, I have a financial interest in Collegium Pharmaceutical as an owner of less than 0.3% of the outstanding shares of the company.

3. Collegium has asked me to render an opinion on the non-obviousness of the modified release milnacipran formulation defined by the claims in U.S.S.N. 10/690,947 filed October 22, 2003. In order to render this opinion, I have reviewed the published patent application (Appendix B), the amendment and response filed on April 17, 2007 (Appendix C), and the Office Action mailed September 20, 2007 and references cited therein (Appendix D).

4. It is well known that Milnacipran (Ixel®, Pierre Fabre) which is available as an antidepressant outside of the US has demonstrated numerous adverse reactions in human clinical trials with side effects increasing with an increasing dose. Given that the side effects associated with Milnacipran administration are well pronounced even at the fairly low daily doses (i.e., 50 mg per day) administered twice-a-day (as it can be seen from Table 1 of U.S.S.N. 10/690,947), it was not obvious how to develop a once-a-day formulation that would deliver a therapeutic Milnacipran dose and demonstrate diminished incidence and reduced intensity of side effects relative to the immediate release product. This is especially a problem in that the drug is being developed in the US

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for the treatment of Fibromyalgia and recent published Phase III clinical trial data has shown the need to use doses as high as 200 mg per day. In these trials, 200 mg of milnacipran per day administered twice-a-day in an immediate release formulation. The incidence of nausea and vomiting was in the range of 40%. Traditionally, when a twice-a-day immediate release formulation shows an acceptable side effect profile and once-a-day formulation of the same drug is desired, an extended release formulation is the choice of one ordinarily skilled in the art. It is important to note that milnacipran is a very unique molecule in that it is a norepinephrine serotonin reuptake inhibitors or NSRI (as compared to a selective serotonin reuptake inhibitor (SSRI)) and has a norepinephrine (NE) to serotonin reuptake (5-HT) blockade ratio that is 2:1. This results in some unique tolerability challenges compared to the better known SSRI's (e.g., fluoxetine). It was only through the extraordinary understanding of the pharmacology and pharmacokinetics of (NSRI's) and intuition of the inventors that it was determined that based upon the published milnacipran side effect data that the side effects may be both locally *and* centrally mediated. This led to the design of a customized modified (delayed and extended) formulation of milnacipran that combined a delayed release component to alleviate locally mediated side effects with an extended release formulation that lowered the slope of the plasma curve and increased  $T_{max}$  to effectively decrease centrally mediated side effects and provided for a once-a-day administration of the drug. As evidenced by the small yet confirmatory clinical trial, the delayed and extended release once-a-day formulation resulted in a favorable tolerability profile. Moreover, the unmet long-standing need for Milnacipran once-a-day formulation with diminished incidence and reduced intensity relative to one or more immediate release Milnacipran side effects

demonstrates the complexity of the problem and characterizes a skill set that is above of that of an ordinary skilled in the art required to solve it.

5. Only through a careful understanding of the relationship of the therapeutic dose to plasma levels, knowledge of the pharmacology of NSRI's and the onset of side effects could a modified dosage form be designed that reduces, diminishes, or prevents locally mediated and centrally mediated side effects while still providing a high enough dose to be efficacious. The present application discloses the pharmacokinetic profiles necessary to achieve this delicate balance between maintaining a therapeutically effective plasma level and reducing the incidence and/or severity of unwanted side effects and discloses the formulations necessary to achieve these profiles. These modified release formulations, their pharmacokinetic profiles and their effectiveness in reducing the incidence of common milnacipran side effects is generally demonstrated by reference to the data attached in Appendix E. This data demonstrates that the formulations provide *in vivo* drug plasma levels characterized by a  $T_{max}$  at 4-10 hours and an approximately linear drop-off thereafter and a  $C_{max}$  below 3,000 ng/ml. Further, **none** of the subjects at any given time during the bioavailability study conducted under **fasting** conditions experienced any of the common side effects of milnacipran such as nausea, vomiting, sweating and tremors (it is important to note that Milnacipran side effects are the most pronounced under **fasting** conditions). These data establish that the presently claimed modified release formulations are effective to deliver efficacious levels of milnacipran over an extended period of time while diminishing incidence and reducing intensity relative to one or more immediate release Milnacipran side effects.

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6. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

12 / 14 / 07  
Date

Martin Keller  
Dr. Martin Keller

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Appendix C: Amendment and response filed April 17, 2007

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**AMENDMENT AND RESPONSE**

Sir:

Responsive to the Office Action mailed on January 17, 2007, please amend the application as follows. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

**Amendment**

**In the Claims**

1-22. Canceled

23. (currently amended) A method of making a milnacipran formulation comprising providing ~~the formulation of claim 1~~ a milnacipran formulation that provides delayed or extended release of milnacipran to produce a therapeutic effect over approximately 24 hours when administered to a patient in need, with diminished incidence or reduced intensity relative to one or more immediate release milnacipran side effects.

24. (currently amended) A method for delivering a therapeutic dose of milnacipran to a patient in need thereof, with diminished incidence or reduced intensity of common milnacipran side effects, comprising administering to the patient in need thereof ~~the milnacipran formulation of claim 1~~ a milnacipran formulation that provides delayed or extended release of milnacipran to produce a therapeutic effect over approximately 24 hours when administered to a patient in need, with diminished incidence or reduced intensity relative to one or more immediate release milnacipran side effects.

25. (new) The method according to Claim 24, wherein the side effect is nausea.

26. (new) The method according to Claim 24, wherein the side effects are selected from the group consisting of vomiting, headache, tremulousness, anxiety, panic attacks, palpitations, urinary retention, orthostatic hypotension, diaphoresis, chest pain, rash, weight gain, back pain, constipation, vertigo, increased sweating, agitation, hot

flushes, tremors, fatigue, somnolence, dyspepsia, dysoria, nervousness, dry mouth, abdominal pain, irritability, and insomnia.

27. (new) The method according to Claim 24, wherein the formulation has a milnacipran release profile that is characterized by release of less than approximately 10% of the total dose over a period up to four hours, followed by a slow or extended drug release.

28. (new) The method according to Claim 27, wherein the defined period of time is between approximately four and approximately twenty-four hours.

29. (new) The method according to Claim 24, wherein the formulation provides milnacipran blood plasma levels that are characterized by  $T_{\max}$  at 4-10 hours, and  $C_{\max}$  below approximately 3000 ng/ml.

30. (new) The method according to Claim 29, wherein the formulation provides milnacipran blood plasma levels that are characterized by  $C_{\max}$  below approximately 2000 ng/ml.

31. (new) The method according to Claim 24, wherein the formulation provides milnacipran blood plasma levels that are characterized by  $C_{\max}$  below approximately 1000 ng/ml.

32. (new) The method according to Claim 24, wherein the formulation further comprises at least one other active compound selected from the group consisting of analgesics, anti-inflammatory drugs, antipyretics, antidepressants, antiepileptics, antihistamines, antimigraine drugs, antimuscarinics, anxiolytics, sedatives, hypnotics, antipsychotics, bronchodilators, anti asthma drugs, cardiovascular drugs, corticosteroids,



dopaminergics, electrolytes, gastro-intestinal drugs, muscle relaxants, nutritional agents, vitamins, parasympathomimetics, stimulants, anorectics, and anti-narcoleptics.

33. (new) The method according to Claim 32, wherein the formulation comprises compounds selected from the group consisting of aceclofenac, acetaminophen, adomexetine, almotriptan, alprazolam, amantadine, amcinonide, aminocyclopropane, amitriptyline, amolodipine, amoxapine, amphetamine, aripiprazole, aspirin, atomoxetine, azasetron, azatadine, beclomethasone, benactyzine, benoxaprofen, bermoprofen, betamethasone, bicifadine, bromocriptine, budesonide, buprenorphine, bupropion, buspirone, butorphanol, butriptyline, caffeine, carbamazepine, carbidopa, carisoprodol, celecoxib, chlordiazepoxide, chlorpromazine, choline salicylate, citalopram, clomipramine, clonazepam, clonidine, clonitazene, clorazepate, clotiazepam, cloxazolam, clozapine, codeine, corticosterone, cortisone, cyclobenzaprine, cyproheptadine, demexiptiline, desipramine, desomorphine, dexamethasone, dexanabinol, dextroamphetamine sulfate, dextromoramide, dextropropoxyphene, dezocine, diazepam, dibenzepin, diclofenac sodium, diflunisal, dihydrocodeine, dihydroergotamine, dihydromorphine, dimetacrine, divalproxex, dizatriptan, dolasetron, donepezil, dothiepin, doxepin, duloxetine, ergotamine, escitalopram, estazolam, ethosuximide, etodolac, femoxetine, fenamates, fenoprofen, fentanyl, fludiazepam, fluoxetine, fluphenazine, flurazepam, flurbiprofen, flutazolam, fluvoxamine, frovatriptan, gabapentin, galantamine, gepirone, ginko bilboa, granisetron, haloperidol, huperzine A, hydrocodone, hydrocortisone, hydromorphone, hydroxyzine, ibuprofen, imipramine, indiplon, indomethacin, indoprofen, iprindole, ipsapirone, ketaserin, ketoprofen, ketorolac, lesopitron, levodopa, lipase, lofepramine, lorazepam, loxapine, maprotiline, mazindol,

mefenamic acid, melatonin, melitracen, memantine, meperidine, meprobamate, mesalamine, metapramine, metaxalone, methadone, methadone, methamphetamine, methocarbamol, methyl dopa, methylphenidate, methylsalicylate, methysergid(e), metoclopramide, mianserin, mifepristone, milnacipran, minaprine, mirtazapine, moclobemide, modafinil, molindone, morphine, morphine hydrochloride, nabumetone, nadolol, naproxen, naratriptan, nefazodone, neurontin, nomifensine, nortriptyline, olanzapine, olsalazine, ondansetron, opipramol, orphenadrine, oxaflozane, oxaprazin, oxazepam, oxitriptan, oxycodone, oxymorphone, pancrelipase, parecoxib, paroxetine, pemoline, pentazocine, pepsin, perphenazine, phenacetin, phendimetrazine, phenmetrazine, phenylbutazone, phenytoin, phosphatidylserine, pimozide, pirlindole, piroxicam, pizotifen, pizotyline, pramipexole, prednisolone, prednisone, pregabalin, propanolol, propizepine, propoxyphene, protriptyline, quazepam, quinupramine, reboxitine, reserpine, risperidone, ritanserin, rivastigmine, rizatriptan, rofecoxib, ropinirole, rotigotine, salsalate, sertraline, sibutramine, sildenafil, sulfasalazine, sulindac, sumatriptan, tacrine, temazepam, tetrabenazine, thiazides, thioridazine, thiothixene, tiapride, tiasipirone, tizanidine, tofenacin, tolmetin, toloxatone, topiramate, tramadol, trazodone, triazolam, trifluoperazine, trimethobenzamide, trimipramine, tropisetron, valdecoxib, valproic acid, venlafaxine, viloxazine, vitamin E, zimeldine, ziprasidone, zolmitriptan, zolpidem, zopiclone and isomers, salts, and combinations thereof.

34. (new) The method according to Claim 24, wherein the milnacipran is in the form of a therapeutically equivalent dose of dextrogyral or levogyral enantiomers of the milnacipran or pharmaceutically acceptable salts thereof.

35. (new) The method according to Claim 24, wherein the milnacipran is in the form of a therapeutically equivalent dose of a mixture of milnacipran enantiomers or pharmaceutically acceptable salts thereof.

36. (new) The method according to Claim 24, wherein the milnacipran is in the form of a therapeutically equivalent dose of the active metabolite of milnacipran or pharmaceutically acceptable salts thereof.

37. (new) The method according to Claim 24, wherein the milnacipran is in the form of a therapeutically equivalent dose of para-hydroxy-milnacipran (F2782) or pharmaceutically acceptable salts thereof.

38. (new) The method according to Claim 24, wherein the formulation further comprises an enteric coating.

39. (new) The method according to Claim 24, wherein the formulation comprises a milnacipran dose from 25 to 500 mg.

40. (new) The method according to Claim 24, wherein the formulation comprises a milnacipran dose from 200 to 500 mg.

41. (new) The method according to Claim 40, wherein the formulation comprises 25 to 500 mg milnacipran and 100 to 600 mg modafinil.

### **Remarks**

Claims 1-22 have been canceled. Claim 23 has been amended to recite a method of making a method of making a milnacipran formulation comprising providing a milnacipran formulation that provides delayed or extended release of milnacipran to produce a therapeutic effect over approximately 24 hours when administered to a patient in need, with diminished incidence or reduced intensity relative to one or more immediate release milnacipran side effects. Support for the amendment is found at least in the claims, as originally filed, and the abstract.

Claim 24 has been amended to recite a method for delivering a therapeutic dose of milnacipran to a patient in need thereof, with diminished incidence or reduced intensity of common milnacipran side effects, comprising administering to the patient in need thereof a milnacipran formulation that provides delayed or extended release of milnacipran to produce a therapeutic effect over approximately 24 hours when administered to a patient in need, with diminished incidence or reduced intensity relative to one or more immediate release milnacipran side effects. Support for the amendment is found at least in the claims, as originally filed and the abstract.

New method claims 25-41 have been added, defining the composition used in the method. Support for the amendment is found at least in the claims as originally filed and now cancelled. The table below shows the relationship between new claims 25-41 and canceled claims 1-22.

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New Claim

Canceled Claims

25	2
26	3
27	4
28	5
29	6
30	7
31	8
32	9
33	10
34	11
35	12
36	13
37	14
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39	16
40	17
41	18

**Rejection Under 35 U.S.C. § 102**

Claims 1-24 were rejected under 35 U.S.C. § 102(f) as being unpatentable over copending application U.S.S.N. 10/690,947. Applicants respectfully traverse this rejection.

Analysis

Applicants are submitting a Petition to Correct Inventorship in copending application U.S.S.N. 10/691,936, adding Srinivas G. Rao as an inventor. Dr. Rao is assigning his interest in U.S.S.N. 10/691,936 to Cypress Bioscience, Inc. As a result, the

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present application and U.S.S.N. 10/691,936 will have identity of inventorship and identity of ownership. Accordingly, the Examiner's rejection under 35 U.S.C. § 102(f) is no longer applicable.

### **Double Patenting Rejection**

Claims 1-24 were provisionally rejected under 35 U.S.C. § 101 for alleging claiming the same invention as claims 1-24 of copending Application No. 10/690,947. Applicants respectfully traverse this rejection to the extent it applied to the claims as amended.

Claims 1-22 have been canceled. These claims are being pursued in copending Application No. 10/691,936.

Claims 23 and 24 of the co-pending application which correspond to the claims in this application have been cancelled.

As noted above, Applicants are submitting a Petition to Correct Inventorship in copending application U.S.S.N. 10/691,936 in order to add Srinivas G. Rao as an inventor. Dr. Rao is assigning his interest in U.S.S.N. 10/691,936 to Cypress Bioscience, Inc. As a result, the present application and U.S.S.N. 10/691,936 will have identity of inventorship and identity of ownership. Accordingly, the Examiner's rejection under 35 U.S.C. § 101 is no longer applicable.

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Allowance of claims 23-41, as amended, is respectfully solicited.

Respectfully submitted,

/Michael J. Terapane/  
Michael J. Terapane, Ph.D.  
Reg. No. 57,633

Date: April 17, 2007

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Appendix E: Additional data provided by Collegium with respect to a modified release milnacipran composition

**Example 1: Composition and *In Vitro* Dissolution Profile of the Preferred Formulation**

The composition of the extended release ("ER") core of the final formulation is given in Table 1.

The tablet core was manufactured as follows:

1. Milnacipran hydrochloride and Ethocel® 10 cps were sifted through a #40 screen.
2. The sifted milnacipran and ethocel from step 1 were loaded into a Rapid mixer granulator and mixed for 2 minutes at slow speed.
3. The dry mix from step 2 was granulated with Aquacoat® ECD-30 and the required quantity of water and mixed at slow speed for 2 minutes. The wet mass was passed through a #12 screen.
4. The wet mass from step 3 was dried in a tray oven at 50°C till the moisture content was between 1% and 1.5% by weight.
5. The dried granules from step 4 were passed through a #30 screen.
6. Methocel® K100M and Avicel® PH 102 were sifted through a #40 screen. The dried granules from step 5 and the sifted materials were loaded into a V-cone blender and mixed for 15 minutes without the intensifier bar.
7. Magnesium stearate was sifted through a #40 screen and added to the mixture from step 6. The mixture was mixed in a V-Cone blender for 2 minutes without the intensifier bar.
8. The final blend was compressed into tablets with an average tablet weight of 400 mg using a 10.5 mm round standard concave punch at a hardness of 10-12 Kp.



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Table 1. Composition of ER core (Lot #18)

No.	Ingredient	Quantity per tablet	Quantity per 2,000 tablets
1	Milnacipran HCl	120 mg	240 g
2	Ethocel® 10 cps	52 mg	104 g
3	Aquacoat® ECD 30	6 mg	40 g
4	Purified water	q.s.	3 ml
5	Methocel® K 100 M premium	35 mg	70 g
6	Avicel® PH 102	181 mg	362 g
7	Magnesium stearate	6 mg	12 g
	ER core weight	400 mg	

Milnacipran ER cores were coated with Opadry® 7006 (seal coat) up to 2% weight gain and further coated with Acryl-Eze® 93018359 White (delayed release coat) up to 8% weight gain. The final weight of the DR-ER tablet was 441 mg.

The coating parameters are shown in the table below:

Parameter	Seal coat	Over coat
Coating equipment	Ganscoater	Ganscoater
Quantity of tablets	600 g	612 g
Pan speed	11-12 rpm	11 – 12 rpm
Spray rate	2 g / min	1.5-2 g / min
Inlet temperature	70°C	70°C
Exhaust temp.	41°C	40°C
Spray off time	1 second	1 second
Spray on time	300 seconds	300 seconds
Pressure	3 kg / cm <sup>2</sup>	3 kg / cm <sup>2</sup>
Weight gain	2%	8%

***In vitro* dissolution data for 120 mg Milnacipran HCl DR-ER tablet**

A USP dissolution Apparatus I (rotating baskets) at 100 rpm was used for the dissolution experiments. The dissolution media was 0.1 N HCl for the first 2 hours followed by pH 6.8 phosphate buffer. Values given below are the average of three independent dissolution experiments. All dissolution tests were conducted at 37°C.

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HPLC analysis was used to determine percent drug release. Milnacipran released from the tablet (% of total dose) is given as a function of the incubation time. The *in vitro* dissolution curve is given in Figure 1.

Dissolution Time, hours	2.0	2.5	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	12.0	14.0
Milnacipran Released, % of Total Dose	2	17	30	50	62	73	80	85	90	91	96	96

#### **Example 2: Pharmacokinetic Parameters of Final Formulation in Healthy Human Volunteers**

The Milnacipran DR-ER formulation (Lot #18) described above was tested in a single dose one way 6-patient pilot bioavailability study under **fasting** conditions (Figure 2). The calculated pharmacokinetic parameters were as follows:  $T_{max}$  was  $7 \pm 1$  hours,  $C_{max}$  was  $220 \pm 40$  ng/ml, AUC (0-24) was 2847 ng hr/ml, and AUC (0-inf) was 3084 ng hr/ml (Note that the data for five subjects were used to calculate the values above. The data for the 6<sup>th</sup> subject were not taken into account due to unexplainably low observed milnacipran plasma levels).

An IR milnacipran formulation was previously tested under fed conditions and it was found that administration of 50 mg Milnacipran HCl capsule BID resulted in an AUC (0-24) equal to 2592 ng hr/ml, and an AUC (0-inf) equal 2743 to ng hr/ml. Although no direct comparison can be made with the data obtained in the current study due to different study conditions (fasting vs. fed), the AUCs for DR-ER QD essentially matched the ones for IR BID. The known fact that food has very little influence on milnacipran absorption from IR dosage form further supports this statement.

It is important to note that **none** of the subjects at any given time during the bioavailability study (Lot #18) experienced any of common milnacipran side effects such as nausea, vomiting, sweating and tremors.

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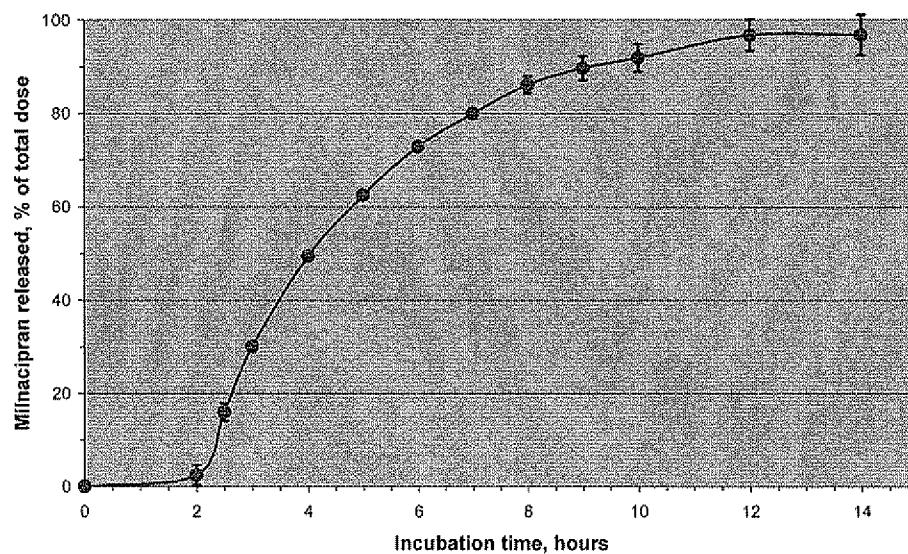


Figure 1

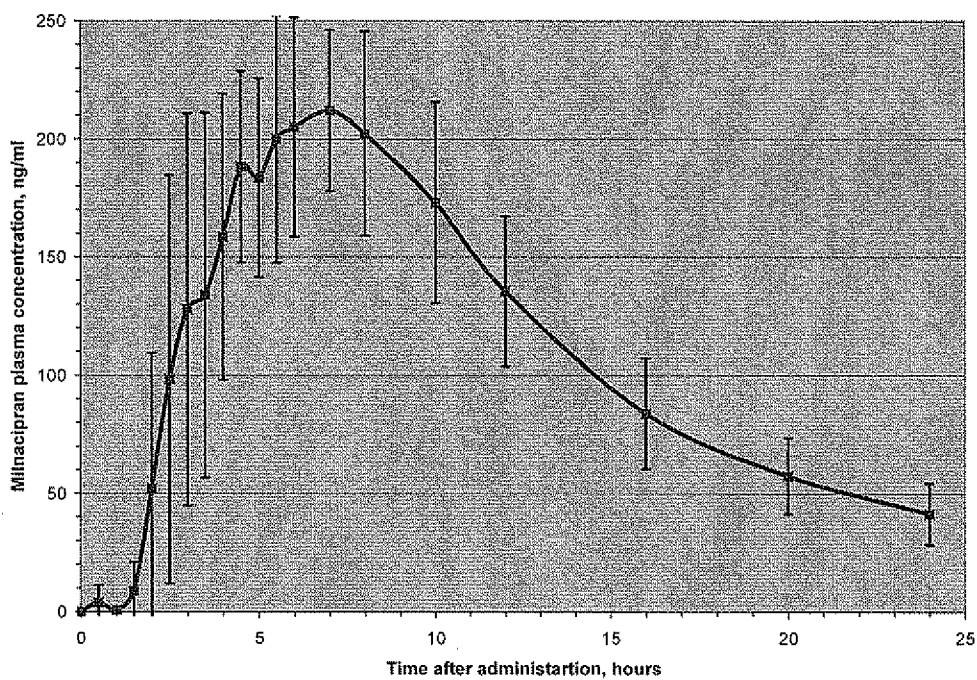


Figure 2

## MARTIN B. KELLER, MD

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### EDUCATION:

- 1968 Dartmouth College (BA)  
Phi Beta Kappa; "High Distinction" in Psychology  
1972 Cornell University (MD)

### POSTGRADUATE TRAINING:

- 1972-1973 Intern in Medicine, Bellevue Medical Center, New York City  
1973-1975 Resident in Psychiatry, Massachusetts General Hospital, Boston  
1975-1976 Chief Resident, Acute Psychiatry Service, Massachusetts General Hospital

### POSTGRADUATE HONORS AND AWARDS:

- 1992 Visiting Professorship in Psychiatry, University of Cincinnati School of Medicine  
1994 Visiting Professorship in Psychiatry, Duke University School of Medicine  
1995-2000 Named in the 1995, 1996, and 1997-1998 editions of *The Best Doctors In America*®, Woodward/White, Inc., and 2000 Edition of *International Directory of Distinguished Leadership*  
1997 American Psychiatric Association (APA) Research Award in recognition of research on the longitudinal course and neuropsychopharmacology of anxiety and mood disorders  
1998 Visiting Professorship in Psychiatry, UCLA  
1998 National Alliance for Research on Schizophrenia and Depression (NARSAD) Lieber Award for research on the causes, psychopathology, treatment, and prevention of depression that leads to advancing our understanding of affective illness and new treatment approaches  
1999 National Depressive and Manic Depressive Association (NDMDA) Gerald R. Klerman Lifetime Research Award for lifetime research contributions to the diagnosis and treatment of depressive and manic-depressive illness  
2001 American College of Psychiatrists (ACP) Mood Disorders Lifetime Research Award for major research contributions to the understanding and treatment of mood disorders  
2003 Edward A. Strecker Award from Pennsylvania Hospital and the University of Pennsylvania Health System for an outstanding contribution to the field of clinical psychiatry in the United States  
2005 Voice of Mental Health Award from The Jed Foundation for contributions in the area of suicide prevention

2006	2005-2006 Best Doctors in America
2007	2007-2008 Best Doctors in America

**PROFESSIONAL LICENSES AND BOARD CERTIFICATION:**

- 1973- Massachusetts Board of Registration in Medicine  
1990- Rhode Island Board of Medical Licensure and Discipline

**ACADEMIC APPOINTMENTS:**

- 1973-1976 Clinical Fellow in Psychiatry, Harvard Medical School  
1976-1982 Instructor in Psychiatry, Harvard Medical School  
1982-1985 Assistant Professor of Psychiatry, Harvard Medical School  
1985-1990 Associate Professor of Psychiatry, Harvard Medical School  
1989- Professor and Chairman, Department of Psychiatry and Human Behavior, Brown University

**HOSPITAL APPOINTMENTS:**

- 1976-1978 Clinical Assistant in Psychiatry, Massachusetts General Hospital  
1979-1981 Assistant in Psychiatry, Massachusetts General Hospital  
1982-1987 Assistant Psychiatrist, Massachusetts General Hospital  
1987-1990 Associate Psychiatrist, Massachusetts General Hospital  
1990-1997 Admitting Staff, Westwood Lodge Hospital  
1989- Executive Psychiatrist-in-Chief at the following Providence, RI, hospitals:
  - Emma Pendleton Bradley Hospital
  - Memorial Hospital
  - Miriam Hospital
  - Rhode Island Hospital
  - Roger Williams General Hospital (until 1996)
  - Providence Veterans Administration Medical Center
  - Women & Infants Hospital
- 1989- Psychiatrist-in-Chief, Butler Hospital, Providence, RI

**OTHER APPOINTMENTS:**

- 1977-1979 Consultant, Harvard School of Public Health  
1977-1989 Consultant, Boston Institute of Psychotherapy  
1982-1989 Consultant, NIMH Research Program on the Psychosocial Treatment of Depression  
1983- Ad hoc grant reviewer for NIMH Initial Review Group, Committees on Psychopathology, Psychopharmacology and Psychosocial Treatments  
1985-1989 Member, Psychopathology and Clinical Biology Research Initial Review Committee, NIMH  
1985-1987 Advisory Committee on Mood Disorders to American Psychiatric Association Task Force on DSM-III-R

- 1986-1987 Editor, Section on Unipolar Disorders for American Psychiatric Association Annual Review of Psychiatry
- 1986-1988 Advisor to the American Psychiatric Association, Committee for Outstanding Achievement Awards
- 1988-1994 Co-chair, American Psychiatric Association Task Force on Mood Disorders for DSM-IV
- 1988- Scientific Advisory Board, National Depressive and Manic Depressive Association (Depression and Bipolar Support Alliance, as of 2004)
- 1988-1994 Chair, Professional Education Committee, National Depressive and Manic Depressive Association
- 1990-1994 Scientific Advisory Board, Clinical Research Center for the Study of Psychotherapy, University of Pennsylvania School of Medicine
- 1991-2001 Member, Executive Committee, Scientific Advisory Board, National Depressive and Manic-Depressive Association
- 1992-1996 Board of Directors, American Society of Clinical Psychopharmacology
- 1992- International Advisory Board, World Psychiatric Association
- 1993-2000 Member, International Committee for the Advancement of Neuroscience (ICANP)
- 1994-2000 External Advisory Committee, Department of Psychiatry, Tufts University, New England Medical Center, Boston, MA
- 1995-1998 Chair, Scientific Advisory Board, National Depressive and Manic-Depressive Association
- 2003- Member, Scientific Council, Research Grants Program, National Alliance for Research on Schizophrenia and Depression (NARSAD)
- 2003-2004 Member, Data Safety Monitoring Board for a Japanese double-blinded study of efficacy of antidepressant Zoloft® vs placebo

## **HOSPITAL COMMITTEES:**

### **Massachusetts General Hospital:**

- 1981-1986 Psychotherapy Task Force, Psychiatry Service
- 1981-1990 Committee for Ambulatory Care Division Unit Directors, Psychiatry Service
- 1982-1986 Residency Training Committee, Psychiatry Service
- 1986-1990 Steering Committee, Psychiatry Service
- 1988-1990 Planning Committee, Psychiatry Service
- 1988-1990 Chair, Psychiatry Service Committee on Research

### **Brown University Affiliated Hospitals:**

- 1989- Chair, Steering Committee, Department of Psychiatry and Human Behavior, Brown University
- 1989- Chair, Policy Management and Advisory Council, Department of Psychiatry and Human Behavior, Brown University

- 1989 Chair, Executive Committee on Research, Department of Psychiatry and Human Behavior, Brown University
- 1993-1996 Member, Research Advisory Committee, Rhode Island Hospital
- 1998- Chair, Lifespan Academic Council
- 1999-2000 Chair, Task Force of Graduate Medical Education for Lifespan Academic Council
- 1999- Chair, Basic Preclinical and Clinical Integrative Neuroscience Program, Department of Psychiatry and Human Behavior, Brown University
- 2000-2002 Chair, Brown Medical School Brain Science Strategic Planning Committee
- 2000- Executive Committee, Brown University Brain Science Program
- 2002- Director, Center for Translational Neuroscience Research Program, Departments of Neurology, Neurosurgery, Psychiatry, and Psychology



**UNIVERSITY COMMITTEES:****Harvard Medical School:**

- 1980-1986      Developed and taught Massachusetts General Hospital Module on Outpatient Psychiatry for Harvard Medical School students
- 1987-1990      AIDS Task Force, Department of Psychiatry
- 1988-1990      Chair, Research Committee, Department of Psychiatry

**Brown University School of Medicine:**

- 1989-            Council of Clinical Chairs
- 1989-            Biomedical Faculty Council
- 1989-            Chairs of Academic Departments
- 1989-            Faculty Executive Council
- 1992-1993      Search Committee for Chair of Department of Surgery
- 1992-1993      Chair, Search Committee for Associate Dean of Medicine
- 1993-1995      Chair, Search Committee for Chair of Department of Medicine
- 1993-            Dean's Committee, Brown University School of Medicine Veterans Administration Medical Center
- 1999-            Steering Committee for School of Medicine, Strategic Planning
- 1999-2000      Member, Search Committee, Director of Alcohol Study Center
- 1999-2001      Member, Search Committee, Chair of Psychiatry, Providence Veterans Administration Hospital.
- 2000-2001      Member, Search Committee, Chair of the Department of Family Medicine
- 2004-2005      Chair, Task Force on Medical Student Clerkship Evaluation

**Brown University:**

- 2004-2006      Chair, Committee to Revise Curriculum of Department of Psychology

**REGIONAL, NATIONAL, AND INTERNATIONAL COMMITTEES:**

- 1982- Childhood Affective Disorders Research Consortium, Steering Committee
- 1984 NIMH Consensus Development Conference on Mood Disorders, Panelist
- 1984 NIMH Workshop on Assessing Change in Depressive Disorders, Panelist
- 1985 NIMH Workshop on Dysthymic Disorder, Panelist
- 1987 NIMH Workshop on Comorbidity, Panelist
- 1987 The Royal College of Psychiatrists Symposium on Dysthymic Disorder, Panelist
- 1988 World Psychiatric Association Advances in the Study of Unipolar Depression, Panelist
- 1989 NIMH Conference on the Treatment of Bipolar Disorder, Panelist
- 1990 NIMH Conference on Personality Disorders, Panelist
- 1990-1991 NIMH Consensus Development Conference on Panic Disorder, Planning Committee
- 1991-1993 World Psychiatric Association Presidential Task Force on Long Term Treatment of Panic Disorder, Planning Committee and Member
- 1992 Presidential Task Force on Depression Education, World Psychiatric Association, Co-Chair
- 1993 Educational Task Force on Social Phobia, World Psychiatric Association, Member
- 1993 Educational Task Force on Dysthymia, World Psychiatric Association, Member
- 1994 NIMH Workshop on Panic Disorder: A Life-Course Approach to Recovery, Relapse and Remission, Panelist
- 1994 NIMH Workshop on Treatment of Bipolar Illness: Research Needs and Directions, Panelist
- 1994 NIMH Workshop on Diagnostic Standards, Panelist
- 1995 NIMH Panic Disorder Education Program, Scientific Working Group, Panelist
- 1995 NIMH Conference on Pediatric Psychopharmacology, Rapporteur
- 1996 National Depressive and Manic Depressive Association (NDMDA) Conference on the Undertreatment of Depression, Chair
- 1997 NDMDA Search Committee for Executive Director, Chair
- 1997-2000 Task Force on Pharmacoeconomics, American College of Psychopharmacology
- 1997 External Review Committee, Department of Psychiatry, University of Arizona at Tucson
- 1998-2002 Chair, Research Subcommittee, World Federation of Societies of Biological Psychiatry
- 1999 Co-Chair, Program Committee, American College of Neuropsychopharmacology (ACNP)
- 2000 Chair, Program Committee, American College of Neuropsychopharmacology (ACNP)
- 2000- International Forum on Mood and Anxiety Disorders (FMAD), Executive Committee

- 2001-2003      Program Committee, American College of Psychiatry
- 2002-           Grant proposals reviewer, American Foundation for Prevention of Suicide
- 2002-           Member, Board of Directors, JED Foundation for prevention of suicide
- 2002-           Chair, Scientific Advisory Board, JED Foundation
- 2002-2003      Member, Annenberg Foundation's Adolescent Mental Health Commission

#### **MEMBERSHIP IN PROFESSIONAL SOCIETIES:**

- 1976-1990      Massachusetts Psychiatric Society
- 1976-           Member, American Psychiatric Association
- 1977-           Northeastern Society for Group Psychotherapy
- 1984-           Fellow, American Psychopathological Association
- 1984-           American Association for the Advancement of Science
- 1988-           Association for Research in Nervous and Mental Disease, Inc.
- 1988-1990      Fellow, Massachusetts Psychiatric Society
- 1988-           Fellow, American Psychiatric Association
- 1990-           Fellow, Rhode Island Psychiatric Society
- 1992-           Member, American Society of Clinical Psychopharmacology
- 1993-           Member, Society for Research in Child and Adolescent Psychopathology
- 1994-           Member, American Psychological Society
- 1995-           Member, International Committee for Prevention and Treatment of Depression (PTD)
- 1996-           Member, Rhode Island Medical Society
- 1996-           Member, American Society of Addiction Medicine
- 1997-           Member, Association for Research on Personality Disorders, Inc.
- 1998-           Member, American Medical Association
- 1998-           Fellow, Collegium Internationale Neuro-Psychopharmacologicum
- 1999-           Fellow, American College of Neuropsychopharmacology
- 2003-           Distinguished Fellow, American Psychiatric Association

### **EDITORIAL BOARD APPOINTMENTS:**

1987-	<i>Journal of Clinical Psychiatry</i>
1988-	<i>Journal of Affective Disorders</i>
1992	<i>Communications and Therapeutic Choices in Depression</i>
1993-1996	<i>Anxiety</i>
1994-1995	<i>The Columbia University School of Public Health: Scientific Studies of Alternative Medicine</i>
1996-	<i>Depression and Anxiety</i>
1999-2001	<i>International Advisory Board, Acta Psychiatrica Scandinavica</i>
1999-2001	<i>The World Journal of Biological Psychiatry</i>
2003-	<i>CNS Spectrums</i>

### **EDITORIAL APPOINTMENTS:**

1995-	<i>International Clinical Psychopharmacology</i> (Joint editor)
2002-2006	<i>Neuropsychopharmacology</i> (Field editor for clinical therapeutics)

### **MANUSCRIPT REVIEWER:**

1982-	<i>Archives of General Psychiatry</i>
1982-	<i>American Journal of Psychiatry</i>
1982-	<i>Comprehensive Psychiatry</i>
1982-	<i>Journal of Psychiatric Research</i>
1983-	<i>Journal of the American Medical Association</i>
1983-	<i>Journal of Nervous and Mental Disorders</i>
1984-	<i>Biological Psychiatry</i>
1995-2004	<i>PharmacoEconomics</i>
1995-1999	<i>ADIS International</i>
1995-	<i>Journal of Geriatric Psychiatry and Neurology</i>

### **MAJOR RESEARCH INTERESTS:**

- Psychobiology of affective disorders in adults, adolescents, and children
- Reliability in assessment of psychopathology
- Prospective longitudinal course of affective disorders, eating disorders, anxiety disorders, obsessive compulsive disorders and personality disorders in adults, adolescents and children
- Design and implementation of multi-site randomized clinical trials of bipolar disorder, major depression, double depression, and anxiety disorders in adults and adolescents with psychotherapy and pharmacotherapy, focusing on continuation and maintenance studies
- Virtual reality treatment of Post Traumatic Stress Disorder.

**ORIGINAL PUBLICATIONS IN PEER-REVIEWED JOURNALS:**

1. Keller MB, Lavori PW, Andreasen NC, Grove WM, Shapiro RW, Scheftner W, McDonald-Scott P. Test-retest reliability of assessing psychiatrically ill patients in a multi-center design. *J Psychiatr Res.* 1981;16(4):213-27.
2. Keller MB, Lavori PW, McDonald-Scott P, Scheftner WA, Andreasen NC, Shapiro RW, Croughan J. Reliability of lifetime diagnoses and symptoms in patients with a current psychiatric disorder. *J Psychiatr Res.* 1981;16(4):229-40.
3. Andreasen NC, Grove WM, Shapiro RW, Keller MB, Hirschfeld RM, McDonald-Scott P. Reliability of lifetime diagnosis. A multicenter collaborative perspective. *Arch Gen Psychiatry.* 1981 Apr;38(4):400-5.
4. Grove WM, Andreasen NC, McDonald-Scott P, Keller MB, Shapiro RW. Reliability studies of psychiatric diagnosis. Theory and practice. *Arch Gen Psychiatry.* 1981 Apr;38(4):408-13.
5. Shapiro RW, Keller MB. Initial 6-month follow-up of patients with major depressive disorder. A preliminary report from the NIMH collaborative study of the psychobiology of depression. *J Affect Disord.* 1981 Sep;3(3):205-20.
6. Keller MB, Manschreck TC. The bedside mental status examination – reliability and validity. *Compr Psychiatry.* 1981 Sep-Oct;22(5):500-11.
7. Keller MB, Shapiro RW. Major depressive disorder. Initial results from a one-year prospective naturalistic follow-up study. *J Nerv Ment Dis.* 1981 Dec;169(12):761-8.
8. Keller MB, Shapiro RW. "Double depression": superimposition of acute depressive episodes on chronic depressive disorders. *Am J Psychiatry.* 1982 Apr;139(4):438-42.
9. Andreasen NC, McDonald-Scott P, Grove WM, Keller MB, Shapiro RW, Hirschfeld RM. Assessment of reliability in multicenter collaborative research with a videotape approach. *Am J Psychiatry.* 1982 Jul;139(7):876-82.
10. Keller MB, Shapiro RW, Lavori PW, Wolfe N. Recovery in major depressive disorder: analysis with the life table and regression models. *Arch Gen Psychiatry.* 1982 Aug;39(8):905-10.
11. Keller MB, Shapiro RW, Lavori PW, Wolfe N. Relapse in major depressive disorder: analysis with the life table. *Arch Gen Psychiatry.* 1982 Aug;39(8):911-5.
12. Keller MB, Klerman GL, Lavori PW, Fawcett JA, Coryell W, Endicott J. Treatment received by depressed patients. *JAMA.* 1982 Oct 15;248(15):1848-55.
13. Keller MB, Lavori PW, McDonald-Scott P, Endicott J, Andreasen N, Van Eerdewegh MM. The reliability of retrospective treatment reports. *Psychiatry Res.* 1983 May;9(1):81-8.

14. Keller MB, Lavori PW, Endicott J, Coryell W, Klerman GL. "Double depression": two-year follow-up. *Am J Psychiatry*. 1983 Jun;140(6):689-94.
15. Hirschfeld RM, Klerman GL, Clayton PJ, Keller MB, McDonald-Scott P, Larkin BH. Assessing personality: effects of the depressive state on trait measurement. *Am J Psychiatry*. 1983 Jun;140(6):695-9.
16. Beardslee WR, Bemporad J, Keller MB, Klerman GL. Children of parents with major affective disorder: a review. *Am J Psychiatry*. 1983 Jul;140(7):825-32.
17. Hirschfeld RM, Klerman GL, Clayton PJ, Keller MB. Personality and depression. Empirical findings. *Arch Gen Psychiatry*. 1983 Sep;40(9):993-8.
18. Keller MB. Double depression: Implications for clinical practice. (La double depression: implications cliniques). *Medecine et Hygiene*. 1983 Oct 19;41(1535):3558-62.
19. Keller MB, Lavori PW, Lewis CE, Klerman GL. Predictors of relapse in major depressive disorder. *JAMA*. 1983 Dec 23-30;250(24):3299-304.
20. Lavori PW, Keller MB, Klerman GL. Relapse in affective disorders: a reanalysis of the literature using life table methods. *J Psychiatr Res*. 1984;18(1):13-25.
21. Lavori PW, Keller MB, Roth SL. Affective disorders and ABO blood groups: new data and a reanalysis of the literature using the logistic transformation of proportions. *J Psychiatr Res*. 1984;18(2):119-29.
22. Keller MB, Lavori PW. Double depression, major depression, and dysthymia: distinct entities or different phases of a single disorder? *Psychopharmacol Bull*. 1984 Summer;20(3):399-402.
23. Coryell W, Endicott J, Reich T, Andreasen N, Keller M. A family study of bipolar II disorder. *Br J Psychiatry*. 1984 Jul;145:49-54.
24. Coryell W, Lavori P, Endicott J, Keller M, VanEerdewegh M. Outcome in schizoaffective, psychotic, and nonpsychotic depression. Course during a six- to 24-month follow-up. *Arch Gen Psychiatry*. 1984 Aug;41(8):787-91.
25. Keller MB, Klerman GL, Lavori PW, Coryell W, Endicott J, Taylor J. Long-term outcome of episodes of major depression. Clinical and public health significance. *JAMA*. 1984 Aug 10;252(6):788-92.
26. Rice J, Reich T, Andreasen NC, Lavori PW, Endicott J, Clayton PJ, Keller MB, Hirschfeld RM, Klerman GL. Sex-related differences in depression. Familial evidence. *J Affect Disord*. 1984 Dec;7(3-4):199-210.
27. Hirschfeld RM, Klerman GL, Clayton PJ, Keller MB, Andreasen NC. Personality and gender-related differences in depression. *J Affect Disord*. 1984 Dec;7(3-4):211-21.

28. Beardslee WR, Keller MB, Klerman GL. Children of parents with affective disorder. *Int J Fam Psychiatry*. 1985;6(3):283-99.
29. Endicott J, Nee J, Andreasen N, Clayton P, Keller M, Coryell W. Bipolar II. Combine or keep separate? *J Affect Disord*. 1985 Jan-Feb;8(1):17-28.
30. Kashani JH, Keller MB, Solomon N, Reid JC, Mazzola D. Double depression in adolescent substance users. *J Affect Disord*. 1985 Mar-Apr;8(2):153-7.
31. NIMH/NIH. NIMH/NIH Consensus Development Conference statement. Mood disorders: pharmacologic prevention of recurrences. Consensus Development Panel. *Am J Psychiatry*. 1985 Apr;142(4):469-76.
32. Beardslee WR, Klerman GL, Keller MB, Lavori PW, Podorefsky DL. But are they cases? Validity of DSM-III major depression in children identified in a family study. *Am J Psychiatry*. 1985 Jun;142(6):687-91.
33. Coryell W, Endicott J, Keller M, Andreasen NC. Phenomenology and family history in DSM-III psychotic depression. *J Affect Disord*. 1985 Jul;9(1):13-8.
34. Coryell W, Endicott J, Andreasen N, Keller M. Bipolar I, bipolar II, and nonbipolar major depression among the relatives of affectively ill probands. *Am J Psychiatry*. 1985 Jul;142(7):817-21.
35. Klerman GL, Lavori PW, Rice J, Reich T, Endicott J, Andreasen NC, Keller MB, Hirschfeld RM. Birth-cohort trends in rates of major depressive disorder among relatives of patients with affective disorder. *Arch Gen Psychiatry*. 1985 Jul;42(7):689-93.
36. Hirschfeld RM, Klerman GL, Andreasen NC, Clayton PJ, Keller MB. Situational major depressive disorder. *Arch Gen Psychiatry*. 1985 Nov;42(11):1109-14.
37. Keller MB, Lavori PW, Rice J, Coryell W, Hirschfeld RM. The persistent risk of chronicity in recurrent episodes of nonbipolar major depressive disorder: a prospective follow-up. *Am J Psychiatry*. 1986 Jan;143(1):24-8.
38. Endicott J, Nee J, Coryell W, Keller M, Andreasen N, Croughan J. Schizoaffective, psychotic, and nonpsychotic depression: differential familial association. *Compr Psychiatry*. 1986 Jan-Feb;27(1):1-13.
39. Andreasen NC, Scheftner W, Reich T, Hirschfeld RM, Endicott J, Keller MB. The validation of the concept of endogenous depression. A family study approach. *Arch Gen Psychiatry*. 1986 Mar;43(3):246-51.
40. Keller MB, Lavori PW, Klerman GL, Andreasen NC, Endicott J, Coryell W, Fawcett J, Rice JP, Hirschfeld RM. Low levels and lack of predictors of somatotherapy and psychotherapy received by depressed patients. *Arch Gen Psychiatry*. 1986 May;43(5):458-66.

41. Hirschfeld RM, Klerman GL, Andreasen NC, Clayton PJ, Keller MB. Psycho-social predictors of chronicity in depressed patients. *Br J Psychiatry*. 1986 Jun;148:648-54.
42. Keller MB, Lavori PW, Coryell W, Andreasen NC, Endicott J, Clayton PJ, Klerman GL, Hirschfeld RM. Differential outcome of pure manic, mixed/cycling, and pure depressive episodes in patients with bipolar illness. *JAMA*. 1986 Jun 13;255(22):3138-42.
43. Hirschfeld RM, Klerman GL, Keller MB, Andreasen NC, Clayton PJ. Personality of recovered patients with bipolar affective disorder. *J Affect Disord*. 1986 Jul-Aug;11(1):81-9.
44. Keller MB, Beardslee WR, Dorer DJ, Lavori PW, Samuelson H, Klerman GR. Impact of severity and chronicity of parental affective illness on adaptive functioning and psychopathology in children. *Arch Gen Psychiatry*. 1986 Oct;43(10):930-7.
45. Rice JP, McDonald-Scott P, Endicott J, Coryell W, Grove WM, Keller MB, Altis D. The stability of diagnosis with an application to bipolar II disorder. *Psychiatry Res*. 1986 Dec;19(4):285-96.
46. Kaplan BJ, Beardslee WR, Keller MB. Intellectual competence in children of depressed parents. *J Clin Child Psychol*. 1987;16(2):158-63.
47. Brotman AW, Pascarzi GA, Keller MB, Dorer DJ, Eisenthal S. Patients treated with psychodynamic psychotherapy by residents at Massachusetts General Hospital. *J Psychiatr Educ*. 1987;11(4):233-42.
48. Herzog DB, Keller MB, Lavori PW, Ott IL, Bridges AC. Social impairment in bulimia. *Int J Eating Disord*. 1987;6(6):741-7.
49. Biederman J, Keller M, Lavori P, Harmatz J, Knee D, Dubey D, Yunis E. HLA haplotype A26-B38 in affective disorders: lack of association. *Biol Psychiatry*. 1987 Feb;22(2):221-4.
50. Coryell W, Grove W, vanEerdewegh M, Keller M, Endicott J. Outcome in RDC schizo-affective depression: the importance of diagnostic subtyping. *J Affect Disord*. 1987 Jan-Feb;12(1):47-56.
51. Lavori PW, Klerman GL, Keller MB, Reich T, Rice J, Endicott J. Age-period-cohort analysis of secular trends in onset of major depression: findings in siblings of patients with major affective disorder. *J Psychiatr Res*. 1987;21(1):23-35.
52. Coryell W, Endicott J, Keller M. The importance of psychotic features to major depression: course and outcome during a 2-year follow-up. *Acta Psychiatr Scand*. 1987 Jan;75(1):78-85.
53. Coryell W, Andreasen NC, Endicott J, Keller M. The significance of past mania or hypomania in the course and outcome of major depression. *Am J Psychiatry*. 1987 Mar;144(3):309-15.



54. Young MA, Keller MB, Lavori PW, Scheftner WA, Fawcett JA, Endicott J, Hirschfeld RM. Lack of stability of the RDC endogenous subtype in consecutive episodes of major depression. *J Affect Disord.* 1987 Mar-Apr;12(2):139-43.
55. Grove WM, Andreasen NC, Young M, Endicott J, Keller MB, Hirschfeld RM, Reich T. Isolation and characterization of a nuclear depressive syndrome. *Psychol Med.* 1987 May;17(2):471-84.
56. Keller MB, Lavori PW, Friedman B, Nielsen E, Endicott J, McDonald-Scott P, Andreasen NC. The Longitudinal Interval Follow-up Evaluation. A comprehensive method for assessing outcome in prospective longitudinal studies. *Arch Gen Psychiatry.* 1987 Jun;44(6):540-8.
57. Andreasen NC, Grove WM, Endicott J, Coryell WH, Scheftner WA, Hirschfeld RMA, Keller MB. The phenomenology of depression. *Psychiatry Psychobiol.* 1988;3:1-10.
58. Keller MB. Undertreatment of major depression. *Psychopharmacol Bull.* 1988;24(1):75-80.
59. Herzog DB, Keller MB, Lavori PW, Ott IL. Short-term prospective study of recovery in bulimia nervosa. *Psychiatry Res.* 1988 Jan;23(1):45-55.
60. Lavori PW, Keller MB, Endicott J. Improving the validity of FH-RDC diagnosis of major affective disorder in un interviewed relatives in family studies: a model based approach. *J Psychiatr Res.* 1988;22(4):249-59.
61. Herzog DB, Keller MB, Lavori PW. Outcome in anorexia nervosa and bulimia nervosa. A review of the literature. *J Nerv Ment Dis.* 1988 Mar;176(3):131-43.
62. Coryell W, Endicott J, Andreasen NC, Keller MB, Clayton PJ, Hirschfeld RM, Scheftner WA, Winokur G. Depression and panic attacks: the significance of overlap as reflected in follow-up and family study data. *Am J Psychiatry.* 1988 Mar;145(3):293-300.
63. Lavori PW, Keller MB. Improving the aggregate performance of psychiatric diagnostic methods when not all subjects receive the standard test. *Stat Med.* 1988 Jul;7(7):727-37.
64. Keller MB, Beardslee W, Lavori PW, Wunder J, Drs DL, Samuelson H. Course of major depression in non-referred adolescents: a retrospective study. *J Affect Disord.* 1988 Nov-Dec;15(3):235-43.
65. Lavori PW, Keller MB, Beardslee WR, Dorer DJ. Affective disorder in childhood: separating the familial component of risk from individual characteristics of children. *J Affect Disord.* 1988 Nov-Dec;15(3):303-11.
66. Beardslee WR, Keller MB, Lavori PW, Klerman GK, Dorer DJ, Samuelson H. Psychiatric disorder in adolescent offspring of parents with affective disorder in a non-referred sample. *J Affect Disord.* 1988 Nov-Dec;15(3):313-22.

67. Rice J, Andreasen NC, Coryell W, Endicott J, Fawcett J, Hirschfeld RM, Keller MB, Klerman GL, Lavori P, Reich T, Scheftner WA. NIMH Collaborative Program on the Psychobiology of Depression: clinical. *Genet Epidemiol*. 1989;6(1):179-82.
68. Coryell W, Keller M, Endicott J, Andreasen N, Clayton P, Hirschfeld R. Bipolar II illness: course and outcome over a five-year period. *Psychol Med*. 1989 Feb;19(1):129-41.
69. Hirschfeld RM, Kosier T, Keller MB, Lavori PW, Endicott J. The influence of alcoholism on the course of depression. *J Affect Disord*. 1989 Mar-Jun;16(2-3):151-8.
70. Hasin DS, Endicott J, Keller MB. RDC alcoholism in patients with major affective syndromes: two-year course. *Am J Psychiatry*. 1989 Mar;146(3):318-23.
71. Hirschfeld RM, Klerman GL, Lavori P, Keller MB, Griffith P, Coryell W. Premorbid personality assessments of first onset of major depression. *Arch Gen Psychiatry*. 1989 Apr;46(4):345-50.
72. Keller MB. Current concepts in affective disorders. *J Clin Psychiatry*. 1989 May;50(5):157-62.
73. Coryell W, Endicott J, Keller M, Andreasen N, Grove W, Hirschfeld RM, Scheftner W. Bipolar affective disorder and high achievement: a familial association. *Am J Psychiatry*. 1989 Aug;146(8):983-8.
74. Gelenberg AJ, Kane JM, Keller MB, Lavori P, Rosenbaum JF, Cole K, Lavelle J. Comparison of standard and low serum levels of lithium for maintenance treatment of bipolar disorder. *N Engl J Med*. 1989 Nov 30;321(22):1489-93.
75. Schwartz CE, Dorer DJ, Beardslee WR, Lavori PW, Keller MB. Maternal expressed emotion and parental affective disorder: risk for childhood depressive disorder, substance abuse, or conduct disorder. *J Psychiatr Res*. 1990;24(3):231-50.
76. Winokur G, Coryell W, Keller M, Scheftner WA. Relationship of electroconvulsive therapy to course in affective illness: a collaborative study. *Eur Arch Psychiatry Clin Neurosci*. 1990;240(1):54-9.
77. Young MA, Fogg LF, Scheftner WA, Keller MB, Fawcett JA. Sex differences in the lifetime prevalence of depression: does varying the diagnostic criteria reduce the female/male ratio? *J Affect Disord*. 1990 Mar;18(3):187-92.
78. Coryell W, Keller M, Lavori P, Endicott J. Affective syndromes, psychotic features, and prognosis. I. Depression. *Arch Gen Psychiatry*. 1990 Jul;47(7):651-7.
79. Coryell W, Keller M, Lavori P, Endicott J. Affective syndromes, psychotic features, and prognosis. II. Mania. *Arch Gen Psychiatry*. 1990 Jul;47(7):658-62.

80. Coryell W, Endicott J, Keller M. Outcome of patients with chronic affective disorder: a five-year follow-up. *Am J Psychiatry*. 1990 Dec;147(12):1627-33.
81. Keller MB, Lavori PW, Beardslee WR, Wunder J, Ryan N. Depression in children and adolescents: new data on 'undertreatment' and a literature review on the efficacy of available treatments. *J Affect Disord*. 1991 Mar;21(3):163-71.
82. Keller MB, Baker LA. Bipolar disorder: epidemiology, course, diagnosis, and treatment. *Bull Menninger Clin*. 1991 Spring;55(2):172-81.
83. Herzog DB, Keller MB, Lavori PW, Bradburn IS. Bulimia nervosa in adolescence. *J Dev Behav Pediatr*. 1991 Jun;12(3):191-5.
84. Hasin DS, Endicott J, Keller MB. Alcohol problems in psychiatric patients: 5-year course. *Compr Psychiatry*. 1991 Jul-Aug;32(4):303-16.
85. Keller MB, Russell CW. Refining the concept of dysthymia. *Hosp Community Psychiatry*. 1991 Sep;42(9):892-3, 896.
86. Frank E, Prien RF, Jarrett RB, Keller MB, Kupfer DJ, Lavori PW, Rush AJ, Weissman MM. Conceptualization and rationale for consensus definitions of terms in major depressive disorder. Remission, recovery, relapse, and recurrence. *Arch Gen Psychiatry*. 1991 Sep;48(9):851-5.
87. Coryell W, Endicott J, Keller MB. Predictors of relapse into major depressive disorder in a nonclinical population. *Am J Psychiatry*. 1991 Oct;148(10):1353-8.
88. Clayton PJ, Grove WM, Coryell W, Keller M, Hirschfeld R, Fawcett J. Follow-up and family study of anxious depression. *Am J Psychiatry*. 1991 Nov;148(11):1512-7.
89. Herzog D, Keller MB, Strober M, Yeh C, Pai SY. The current status of treatment for anorexia nervosa and bulimia nervosa. *Int J Eating Disorders*. 1992;12(2):215-220.
90. Keller MB, Herzog DB, Lavori PW, Bradburn IS, Mahoney EM. The naturalistic history of bulimia nervosa: extraordinarily high rates of chronicity, relapse, recurrence, and psychosocial morbidity. *Int J Eating Disord*. 1992;12(1):1-9.
91. Biederman J, Faraone SV, Keenan K, Benjamin J, Krifcher B, Moore C, Sprich-Buckminster S, Ugaglia K, Jellinek MS, Steingard R, Spencer T, Norman D, Kolodny R, Kraus, Perrin J, Keller MB, Tsuang MT. Further evidence for family-genetic risk factors in attention deficit hyperactivity disorder. Patterns of comorbidity in probands and relatives psychiatrically and pediatrically referred samples. *Arch Gen Psychiatry*. 1992 Sep;49(9):728-38.
92. Yonkers KA, Ellison JM, Shera DM, Pratt LA, Langford LM, Cole JO, White K, Lavori PW, Keller MB. Pharmacotherapy observed in a large prospective longitudinal study on anxiety disorders. *Psychopharmacol Bull*. 1992;28(2):131-7.

93. Keller MB, Lavori PW, Beardslee W, Wunder J, Drs DL, Hasin D. Clinical course and outcome of substance abuse disorders in adolescents. *J Subst Abuse Treat.* 1992;9(1):9-14.
94. Coryell W, Winokur G, Keller M, Scheftner W, Endicott J. Alcoholism and primary major depression: a family study approach to co-existing disorders. *J Affect Disord.* 1992 Feb;24(2):93-9.
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49. Boland RJ, Keller MB. Treatment of Depression. In: Schatzberg AF, Nemeroff CB, eds. *Textbook of Psychopharmacology, Third Edition*. Washington, DC: American Psychiatric Publishing, 2004. Chapter 52: 847-64.
50. Boland RJ, Keller MB. Clinical Course in Bipolar Disorder. In: Kasper S, Hirschfeld R. *Handbook of Bipolar Disorder*. New York, NY: Taylor & Francis Group LLC, 2005. Chapter 8: 95-106.
51. Boland RJ, Keller MB. Treatment of Depression. In: Schatzberg AF, Nemeroff CB, eds. *Essentials of Clinical Psychopharmacology, Second Edition*. Washington, DC: American Psychiatric Publishing, 2006. Chapter 31: 465-78.

#### **Other Publications - Editorials, Letters, and Book Reviews:**

1. Keller MB. Reactive depression. *Physician & Patient*. 1983;9-47.
2. Keller MB, Lavori PW, Endicott J, Klerman GL, Coryell W, Fawcett JA. Treatment of depression. *JAMA*. 1983 Apr 8;249(14):1824.
3. Keller MB, Lavori PW, Endicott J, Klerman GL, Coryell W, Fawcett JA. Antidepressant drugs as a cause of death. *JAMA*. 1983 Apr 8;249(14):1826.
4. Keller MB, Lavori PW, Klerman GL, Endicott J, Coryell W, Fawcett JA. Treatment of depression. *JAMA*. 1983;249(18):2457-8.
5. Keller MB. Possible Effects of Rapid Cycling in "Double Depression." *Am J Psychiatry*. 1984 Feb;141(2):328-9.
6. Keller MB. Review of: *The Behavior of Psychiatric Patients: Quantitative Techniques for Evaluation*. Burdock EI, Sudilovsky A, Gershon S, eds. *Am J Psychiatry*. 1984 Feb;141(2):317-8.
7. Keller MB, Friedman BL, Lavori PW. The nature of recovery and relapse in depressive disorders. *Directions in Psychiatry*. 1984;4(18):1-8.
8. Keller MB. Incidence of relapse in depression. *Med Aspects Hum Sex*. 1985;19(9):153-4.
9. Hirschfeld RMA, Keller MB. The clinical course of major depression. *Masters in Psychiatry*. 1985;9-12.

10. Keller MB. Review of: The Affective Disorders. Davis JM, Maas JW, eds. *Am J Psychiatry*. 1985;142(9):1112-3.
11. Keller MB, Lavori PW. Commentary. The adequacy of treating depression. *J Nerv Ment Dis*. 1988 Aug;176(8):471-4.
12. Keller MB, Herzog DB, Lavori PW, Ott IL, Bradburn IS, Mahoney EM. High rates of chronicity and rapidity of relapse in patients with bulimia nervosa and depression. *Arch Gen Psychiatry*. 1989 May;46(5):480-1.
13. Keller MB, Carver A. Review of: Life-span Research on the Prediction of Psychopathology. Erlenmeyer-Kimling L, Miller NE, eds. *Am J Psychiatry*. 1990;147(2):254.
14. Keller MB, Baker LA. The effects of major depression on dysthymia. *Clin Adv Treat Psychiatr Disord*. April/May 1990;4(2):4,7.
15. Keller MB. Depression. Underrecognition and undertreatment by psychiatrists and other health care professionals. *Arch Intern Med*. 1990 May;150(5):946-8.
16. Keller MB. Early results in "landmark" anxiety study. *Anxiety Disorders Association of America Reporter*. 1991 Sep/Oct;2(3):1,4.
17. Keller MB. Panic disorders: introduction. *RI Med*. 1992 May;75(5):233-5.
18. Herzog DB, Keller MB, Lavori PW, Gray HM. A bulimia family survey. *J Am Acad Child Adolesc Psychiatry*. 1992 Nov;31(6):1170-1.
19. Keller MB. HARP study shows medical problems, under-use of behavioral treatment. *Anxiety Disorders Association of America Reporter*. 1993 Winter;4(1):1,10.
20. Keller MB. Overview of depression: chronicity, recurrence, morbidity and the need for maintenance treatment. *RI Med*. 1993 Aug;76(8):381-6.
21. Keller MB. Summary. *Current Therapeutic Res*. 1993 Dec;54(6):850-1.
22. Keller MB, Hanks DL. Psychiatry in the year 2018. *RI Med*. 1994 Jun;77(6):170-2.
23. Keller MB. Long-term treatment of depression. S-7-5. *Eur Neuropsychopharmacol*. 1994 Sep;4(3):205.
24. Keller M. Cross-over studies of chronic resistant depression. S-14-4. *Eur Neuropsychopharmacol*. 1995 Sep;5(3):198-9.
25. Keller MB. Modern approach in the treatment of anxiety associated with depression. SAT-2-3. *Eur Neuropsychopharmacol*. 1995 Sep;5(3):250.
26. Keller M. The role of continuation treatment in chronic depression. SAT-6-3. *Eur Neuropsychopharmacol*. 1995 Sep;5(3):259-60.

27. Keller MB. Mood Disorders: Preface. *Psychiatr Clin North Am*. 1996 Mar;19(1):xi-xii.  
(*Editor of this issue: Martin B. Keller, MD*)
28. Keller MB, Kocsis JH, Thase ME, Gelenberg AJ, Rush AJ, Koran L, Schatzberg A, Russell J, Hirschfeld R, Klein D, McCullough JP, Kornstein S, Fawcett JA, LaVange L, Harrison W. Response to a letter re: Relapse of depressive symptoms after discontinuing sertraline. *JAMA*. 1999;281(4):323-4. Erratum in: *JAMA*. 2000 Jan;283(1):57.
29. Keller MB. Response to a letter re: Nefazodone and psychotherapy and their combination for chronic depression. *N Engl J Med*. 2000;343(14):1041-2.
30. Culpepper L, Keller MB, Smith NL. Diagnosis and treatment of anxiety disorders: A primary care perspective. A Continuing Education Self-Study Program for Physicians. Sponsored by Medical Education Resources, 2000.
31. Solomon DA, Leon AC, Mueller TI, Shea MT, Keller MB. Response to a letter re: Recurrence of affective disorder. *Am J Psychiatry*. 2001 May;158(5):820.
32. Kornstein SG, Schatzberg AF, Thase ME, Yonkers KA, McCullough JP, Keitner GI, Gelenberg AJ, Davis SM, Keller MB. Response to a letter re: Gender differences in treatment response to sertraline versus imipramine in chronic depression. *Am J Psychiatry*. 2001 Sep;158(9):1532-3.
33. Keller MB, Ryan ND, Wagner KD. Response to a letter re: Paroxetine in adolescent major depression. *J Am Acad Child Adolesc Psychiatry*. 2002 Apr;41(4):364.
34. Keller MB, McCafferty JP. Response to a letter re: Paroxetine in the treatment of adolescent major depression. *J Am Acad Child Adolesc Psychiatry*. 2002 Nov;41(11):1270.
35. Keller MB, Ryan ND. Response to a letter re: Paroxetine in the treatment of adolescent major depression. *J Am Acad Child Adolesc Psychiatry*. 2002 Nov;41(11):1271.
36. Keller MB, Ryan ND, Strober M, Weller EB, McCafferty JP, Hagino OR, Birmaher B, Wagner KD. Response to a letter re: Paroxetine in major depression. *J Am Acad Child Adolesc Psychiatry*. 2003 May;42(5):514-5.
37. Dunner DL, Blier P, Keller MB, Pollack MH, Thase ME, Zajecka JM. Preventing Recurrent Depression: Long-Term Treatment for Major Depressive Disorder (from the roundtable meeting.) *J Clin Psychiatry*. 2007 Apr;68(4):619-30.
38. Dunner DL, Blier P, Keller MB, Pollack MH, Thase ME, Zajecka JM. Preventing Recurrent Depression: Long-Term Treatment for Major Depressive Disorder (from the roundtable meeting.) *Prim Care Companion J Clin Psychiatry*. 2007;9(3):214-23.

## **INVITED PRESENTATIONS (SINCE 1997):**

### **1997:**

#### **National Conferences and Grand Rounds**

- "The Long-Term Treatment of Depression." Dallas, Texas. February 7, 1997.
- "The Long-Term Treatment of Depression." Los Angeles, California. February 11, 1997.
- "Brown Brain Science Day," Chairperson. Brown University, Providence, Rhode Island. April 3, 1997.
- "Comorbidity Factors and the Treatment of Depression," Symposium Chairperson. American Psychiatric Association Annual Meeting. San Diego, California. May 17, 1997.
- "Treatment of Chronic Depression," American Psychiatric Association Annual Meeting. San Diego, California. May 20, 1997.
- "Recurrent Unipolar Major Depression is a Life-long Illness that Requires Life-long Treatment. Yes, no, maybe and if only there were one more study . . ." Distinguished Psychiatrist Lecturer, American Psychiatric Association Annual Meeting. San Diego, California. May 22, 1997.
- "The Long-term Treatment of Depression," Advances in Mood Disorders and Schizophrenia: Diagnoses, Biology and Treatment. Annual Symposium for Psychiatry Residents from all US Medical Schools. Palm Beach, Florida. September 5, 1997.
- "The Long-term Treatment of Depression," Long-term Management of Depression Symposium. Boston, Massachusetts. October 3, 1997.
- "Pharmacotherapy of Mood Disorders," Psychopharmacology: An Update Conference. Syracuse, New York, October 16, 1997.
- "Long-term Treatment of Recurrent Unipolar Depression, Major Depression and Chronic Major Depression," Jan Fawcett, MD, 25-Year Celebration. Chicago, Illinois. October 17, 1997.
- "Comorbidity Factors and the Treatment of Depression," Symposium Chairperson, American Psychiatric Association 49th Institute on Psychiatric Services. Washington, DC, October, 25, 1997.
- "What are the Implications of Failing to Achieve Successful Long-term Maintenance of Major Depression?" A Decade of Serotonin Research Neuroscience Conference. Amelia Island, Florida. November, 17, 1997.
- "Sertraline Maintenance Therapy in Chronic Depression," Poster, American College of Neuropsychopharmacology Annual Meeting. Kamuela, Hawaii. December 8, 1997.

**International Conferences**

"The SSRI Revolution: How Far Have We Come?" Symposium Chairperson, 6th World Congress of Biological Psychiatry. Nice, France. June 24, 1997.

"Social Phobia: Five Years of Prospective Data," 6th World Congress of Biological Psychiatry. Nice, France. June 24, 1997.

"Patient Concerns In Chronic Depression: Impact On Adherence To Treatment," Symposium Chairperson. 6th World Congress of Biological Psychiatry. Nice, France. June 25, 1997.

"Double Depression: A Distinctive Subtype of Unipolar Depression," 6th World Congress of Biological Psychiatry. Nice, France. June 26, 1997.

"Social Phobia: Five Years of Prospective Data," 10th European College of Neuropsychopharmacology Congress. Vienna, Austria. September 15, 1997.

"Social Phobia and Panic Disorder: Five Years of Prospective Data," 10th European College of Neuropsychopharmacology Congress. Vienna, Austria. September 15, 1997.

**1998:****National Conferences and Grand Rounds**

1. "Is the Clinical Course of Anxiety Disorders Just Too Much Worrying or a Life-threatening Pernicious Illness?" Dartmouth COOP Annual Meeting. Hanover, New Hampshire. January 30 & Feb 1, 1998.
2. "Is Continuation and Maintenance Treatment Warranted for Unipolar Major Depression? Yes, No, Maybe?" Dartmouth COOP Annual Meeting. Hanover, New Hampshire. January 30 & Feb 1, 1998.
3. "Long-term Treatment of Recurrent and Chronic Depression," Department of Psychiatry Grand Rounds, University of Pennsylvania. Philadelphia, Pennsylvania. April 16, 1998.
4. "Preventing the Recurrence of Chronic Depression," National Psychiatry Speakers Alliance. Toronto, Canada. May 29, 1998.
5. "Epidemiology, Clinical Course and Treatment Efficacy of Chronic Depression," 151st American Psychiatric Association Annual Meeting. Toronto, Canada. May 31, 1998.
6. "Management of Mental Disorders in Baby Boomers and Beyond," Symposium Chairperson, 151st American Psychiatric Association Annual Meeting. Toronto, Canada. May 31, 1998.
7. "Paroxetine and Imipramine in the Treatment of Adolescent Depression," New Research Presentation, 151st American Psychiatric Association Annual Meeting. Toronto, Canada. May 31, 1998.
8. "Long-term Treatment of Recurrent and Chronic Depression," Annual Psychiatry Residents Symposium. Palm Beach, Florida. September 11, 1998.

9. "Long-term Treatment of Recurrent and Chronic Depression," Chairperson, Looking Up: Improving the Management of Depression Faculty Training Meeting. Atlanta, Georgia. September 25-27, 1998.
10. "Long-term Treatment of Chronic and Recurrent Depression," Department of Psychiatry Grand Rounds, Dartmouth College School of Medicine. Hanover, New Hampshire. September 29, 1998.
11. "Depression and its Impact on the Body and Mind," Symposium Chairperson, American Psychiatric Association 50th Institute on Psychiatric Services. Los Angeles, California, October 3, 1998.
12. "New Research Findings in the Course and Treatment of Recurrent and Chronic Depression," American Psychiatric Association 50th Institute on Psychiatric Services. Los Angeles, California. October 3, 1998.

### International Conferences

1. "Long-term Treatment of Recurrent and Chronic Depression," 2nd Worldwide Psychiatry Speakers' Bureau Meeting. Marrakech, Morocco. March 6, 1998.
2. "The Treatment of Depression with Selective Serotonin Reuptake Inhibitors: A Decade of Discovery," Program Chair and Presenter. Berlin, Germany. March 20-23, 1998.
3. "Long-term Treatment of Recurrent Depression," 21st Colloquium Internationale Neuropsychopharmacologicum (CINP) Congress. Glasgow, Scotland. July 14, 1998.
4. "Long-term Treatment of Chronic Depression: Beyond SSRIs," Program Chair and Presenter, 11th European College of Neuropsychopharmacology Congress (ECNP). Paris, France. October 31-November 4, 1998.
5. "Clinical Course, Morbidity and Undertreatment of Panic Disorder and Social Phobia." 11th European College of Neuropsychopharmacology Congress (ECNP). Paris, France. October 31-November 4, 1998.
6. "Treatment of Depression and Management of Side Effects," Program Chair. 11th European College of Neuropsychopharmacology Congress (ECNP). Paris, France. October 31-November 4, 1998.
7. "Social Functioning and Depression: Looking Beyond the Symptoms." Putting Patients First—The Importance of Social Functioning, 11th European College of Neuropsychopharmacology Congress (ECNP). Paris, France. October 31-November 4, 1998.
8. "The Impact of Pharmacotherapy on Social Functioning." Global Taskforce on Social Functioning, 11th European College of Neuropsychopharmacology Congress (ECNP). Paris, France. October 31-November 4, 1998.

### Other Presentations

1. "The Long-term Treatment of Depression," <http://www.cmece.com/courses/psychiatry/ltld/>. Internet CME Presentation, launch date: February 13, 1998.

2. "Current Issues in Antidepressant Treatment: Long-term Treatment of Depression," Program Chair and Presenter. Strategic Implications International Teleconference Series, Spring-Fall 1998.

**1999:****National Conferences and Grand Rounds**

1. "The Diagnosis, Clinical Course and Management of Anxiety Disorders in Psychiatric and Primary Care Settings," Memorial Hospital, Grand Rounds. Pawtucket, Rhode Island. January 14, 1999.
2. "Long-term Treatment of Depression," Harvard University School of Medicine, Grand Rounds. Boston, Massachusetts. January 26, 1999.
3. "Long-term Treatment of Recurrent and Chronic Depression," Harbor/UCLA Medical Center, Grand Rounds. Los Angeles, California. March 24, 1999.
4. "Anxiety Disorders: The Long-term, Naturalistic Course and Outcome and Strategies to Treat Anxiety with Comorbid Depression," Dartmouth School of Medicine, Grand Rounds. Hanover, New Hampshire. March 30, 1999.
5. "Chronic Depression-Psychotherapy and Pharmacotherapy: Additive or Synergistic?" 152nd American Psychiatric Association Annual Meeting. Washington, DC. May 16, 1999.
6. "Management of Mental Disorders in Baby Boomers and Beyond," Symposium Chairperson, 152nd American Psychiatric Association Annual Meeting. Washington, DC. May 18, 1999.
7. "Nefazodone HCL, Cognitive Behavioral Analysis System of Psychotherapy (CBASP) and Combination Therapy for the Acute Treatment of Chronic Depression," New Research Presentation, 152nd American Psychiatric Association Annual Meeting. Washington, DC. May 19, 1999.
8. "Chronic Depression-Psychotherapy and Pharmacotherapy: Additive or Synergistic?" Visiting Faculty Program. New York, New York. September 29, 1999.
9. "What Are the Implications of Failing to Achieve Successful Long-Term Maintenance of Major Depression?" New York University School of Medicine, Grand Rounds. New York, New York. September 30, 1999.
10. "The Efficacy of Psychotherapy and Pharmacotherapy in the Treatment of Chronic Depression," 51st Annual Meeting of the Institute on Psychiatric Services. New Orleans, Louisiana. November 1, 1999.
11. "Chronic Depression-Psychotherapy and Pharmacotherapy: Additive or Synergistic?" Sloan Kettering Hospital, Grand Rounds. New York, New York. November 12, 1999.



### International Conferences

- "The Long-term Treatment of Depression," Monte Carlo. February 26, 1999.
- "Reboxetine: Improving Patients' Energy, Interest and Motivation," Istanbul, Turkey. March 13, 1999.
- "Chronic Depression: Management Strategies," Barcelona, Spain. April 12, 1999.
- "Social Phobia, Panic Disorder, and Generalized Anxiety Disorder: Five Years of Prospective Data," 12<sup>th</sup> European College of Neuropsychopharmacology Congress, London, UK. September 22, 1999.
- "Consequences of Long-Term Anxiety," 12<sup>th</sup> European College of Neuropsychopharmacology Congress, London, UK. September 22, 1999.
- "New Visions in Antidepressant Treatment: The Importance of Early and Sustained Efficacy," 12<sup>th</sup> European College of Neuropsychopharmacology Congress, London, UK. September 24, 1999.

### Other Presentations

- "State-of-the-art Update in the Management of Depression: Long-term Treatment of Depression," Strategic Implications International CME Teleconference Series. Spring-Fall, 1999.
- "Strategies for the Management of Chronic Depression," PsychLINK Live CME television program. March 10, 1999.
- "The Long-term Treatment of Recurrent and Chronic Depression," August A. Fink Foundation CME Teleconference Series. Spring-Fall, 1999.
- "Treating and Living with Affective Disorders," Harbor Healthcare Management CME Symposium. October 7, 1999.

### 2000:

#### National Conferences and Grand Rounds

1. "The Long-Term Treatment of Recurrent and Chronic Depression: Definitive Data and Unresolved Issues," Mt. Sinai Medical Center, Grand Rounds. New York, New York. February 8, 2000.
2. "The Long-Term Treatment of Recurrent and Chronic Depression: Definitive Data and Unresolved Issues," Duke University, Grand Rounds. Raleigh-Durham, North Carolina. March 16, 2000.
3. "The Long-Term Treatment of Recurrent and Chronic Depression: Definitive Data and Unresolved Issues," Johns Hopkins University, Grand Rounds. Baltimore, Maryland. May 2, 2000.
4. "Mood Disorders across the Life Cycle," National Psychiatry Alliance, Chicago, Illinois. May 12, 2000.

5. "Chronic Depression: Preventing Recurrence," National Psychiatry Alliance, Chicago, Illinois. May 12, 2000.
6. "Novel Treatments for Depression" 153rd American Psychiatric Association Annual Meeting. Chicago, Illinois. May 14, 2000.
7. "New Treatment Findings on Combining Pharmacotherapy and Psychotherapy for Chronic Depression" 153rd American Psychiatric Association Annual Meeting. Chicago, Illinois. May 16, 2000.
8. "The Long-Term Treatment of Recurrent and Chronic Depression: Definitive Data and Unresolved Issues," Reading Hospital and Medical Center, Grand Rounds. Reading, Pennsylvania. September 26, 2000.
9. "The Long-Term Treatment of Recurrent and Chronic Depression: Definitive Data and Unresolved Issues," Ohio State University, Grand Rounds. Columbus, Ohio. October 11, 2000.
10. "The Long-Term Treatment of Recurrent and Chronic Depression: Definitive Data and Unresolved Issues," University of Massachusetts Medical Center, Grand Rounds. Worcester, MA. October 12, 2000.
11. "What is the Optimal Treatment for Chronic Depression? Psychotherapy or Pharmacotherapy: Additive or Synergistic?" American Psychiatric Institute 2000 Meeting of the Institute on Psychiatric Services. Philadelphia, Pennsylvania. October 26, 2000.
12. "The Long-Term Treatment of Recurrent and Chronic Depression: Definitive Data and Unresolved Issues," American Psychiatric Institute 2000 Meeting of the Institute on Psychiatric Services. Philadelphia, Pennsylvania. October 26, 2000.

#### International Conferences

1. "State-of-the-art Update in the Management of Depression: Long-term Treatment of Depression," Strategic Implications International CME Teleconference Series, January–April, 2000.
2. "Antidepressant compliance and effective treatment outcome in depression," 23rd Colloquium Internationale Neuropsychopharmacologicum (CINP), Brussels, Belgium. July 10, 2000.
3. "Clinical presentation of generalized anxiety disorder," 23rd Colloquium Internationale Neuropsychopharmacologicum (CINP), Brussels, Belgium. July 11, 2000.
4. "What is the optimal treatment for chronic depression: Psychotherapy and pharmacotherapy: Additive or synergistic?" 23rd Colloquium Internationale Neuropsychopharmacologicum (CINP), Brussels, Belgium. July 11, 2000.
5. "The long-term treatment of chronic major depression and double depression: Psychotherapy and pharmacotherapy," 23rd Colloquium Internationale Neuropsychopharmacologicum (CINP), Brussels, Belgium. July 12, 2000.
6. "Mood and anxiety disorders in the 21<sup>st</sup> century," Ministers of Health Meetings, Seoul, Korea; and Beijing, Shanghai, Hong Kong, Taipei, China. September 3-24, 2000.

## Other Presentations

1. "State-of-the-art Update in the Management of Depression: Long-term Treatment of Depression," Strategic Implications International CME Teleconference Series, January-April, 2000.
2. "Clinical Challenges in the Treatment of Depression," Nationwide Teleconference Series. January 2000.

## 2001:

### National Conferences and Grand Rounds

- "The Long-Term Treatment of Recurrent and Chronic Depression: Definitive Data and Unresolved Issues," Mt. Sinai Medical Center, Grand Rounds, New York, New York. February 8, 2001.
- "The Long-Term Course and Treatment of Chronic Depression with Pharmacotherapy and Psychotherapy in the New Millennium: Where We Are and Where We Should Be Going," American College of Psychiatrists Annual Meeting, Tucson, Arizona. February 22-23, 2001.
- "The Long-Term Treatment of Recurrent and Chronic Depression: Definitive Data and Unresolved Issues," Johns Hopkins University, Grand Rounds. Baltimore, Maryland. May 2, 2001.
- "Mood Disorders Across the Life Cycle," National Psychiatry Alliance, Chicago, Illinois. May 12, 2001.
- "Chronic Depression: Preventing Recurrence," National Psychiatry Alliance, Chicago, Illinois. May 12, 2001.
- "Novel Treatments for Depression" 154th American Psychiatric Association Annual Meeting. New Orleans, Louisiana. May 14, 2000.
- "New Treatment Findings on Combining Pharmacotherapy and Psychotherapy for Chronic Depression" 154th American Psychiatric Association Annual Meeting. New Orleans, Louisiana. May 15, 2001.
- "Social Phobia and Panic Disorder: Five Years of Prospective Data," Global Research on Anxiety and Depression Network Meeting. Washington, DC. May 10-11, 2001.
- "The Diagnosis, Clinical Course, and Management of Depression in Adolescents and Young Adults," Suicide on College Campuses Roundtable, Washington, DC. May 23-24, 2001.
- "Social Phobia: Eight Years of Prospective Data," Global Research on Anxiety and Depression (GRAD), Martha's Vineyard, Massachusetts. October 4-6, 2001.
- "Reality Check: Real-World Considerations in the Treatment of Mood and Anxiety Disorders." Chair of symposium. American Psychiatric Association, Institute of Psychiatric Services Annual Meeting, Orlando, Florida. October 11, 2001.
- "The Long-Term Course and Treatment of Chronic Depression with Pharmacotherapy and Psychotherapy," Stanford University, Grand Rounds, Stanford, California. November 1, 2001.

### International Conferences

1. "Rationale and options for long-term treatment," Budapest, Hungary. March 29-April 1, 2001.

### Other Presentations

"State-of-the-art Update in the Management of Depression: Long-term Treatment of Depression," Strategic Implications International CME Teleconference Series, January-April, 2000.

"Clinical Challenges in the Treatment of Depression," Nationwide Teleconference Series. January 2000.

"Managing Patients with Generalized Anxiety Disorder and Depression," Nationwide teleconference series, February-June, 2001.

"The Chronically Depressed Patient," Online CME Broadcast Program, Neuropsychiatric Institute, University of California at Los Angeles, April 6, 2001.

"The burden of depressive disorders. New standards in psychiatry: Optimizing outcomes." Postgrad Institute for Medicine, Trevese, PA: Summer 2001.

"New options for the treatment of depression." Journal of Clinical Psychiatry Online Insight (Online CME Activity): October 2001.

## 2002:

### National Conferences and Grand Rounds

1. "Clinical Management of Patients Failing to Respond to Monotherapy and Patients with Treatment-Refractory Depression," Global Neuroscience Summit, Scottsdale, Arizona. March 16, 2002.
2. "Mood and Social Anxiety Disorders: Long-term Management and Treatment Strategies," Global Neuroscience Summit, Scottsdale, Arizona. March 17, 2002.
3. "New Advances in the Management of Depression," National Conference of Anxiety Disorders Association of America, Austin, Texas. March 21, 2002.
4. "A Prospective Naturalistic 8-year Follow-up of Panic Disorder and Social Phobia," Keynote address, National Conference of Anxiety Disorders Association of America, Austin, Texas. March 22, 2002.
5. "Pharmacotherapy and Psychotherapy: New data on the Long-term Treatment of Chronic Major Depression," Future Leaders in Psychiatry Meeting, Miami, Florida. April 12, 2002.
6. "Atypical Depression: Overview and New Developments," Discussant, Symposium, 155<sup>th</sup> Annual Meeting of the American Psychiatric Association, Philadelphia, Pennsylvania. May 19, 2002.
7. "Major Depression: Current Treatment Guidelines, Practices and Effectiveness Research," Discussant, Symposium, 155<sup>th</sup> Annual Meeting of the American Psychiatric Association, Philadelphia, Pennsylvania. May 21, 2002.

8. "Exploring the Facets of Depression: Examining Medical and Psychiatric Comorbidities," Chair, Symposium, APA's Institute on Psychiatric Services (IPS) Meeting. Chicago, Illinois. October 11, 2002.
9. "Diagnosis and Treatment of Depression with Comorbid Anxiety (GAD, SAD, or Panic Disorder)," The Primary Care of Mood Disorders Symposium, Primary Medicine Today (Pri-Med) East conference, Boston, Massachusetts. November 7, 2002.
10. "Key Considerations in Choosing an Antidepressant," Primary Care Roundtable on Depression, Boston, Massachusetts. November 22, 2002.

### **International Conferences and Meetings**

Global Neuroscience Summit, Melbourne, Victoria, Australia. February 1-2, 2002:

1. "Clinical Management of Patients Failing to Respond to Monotherapy and Patients with Treatment-Refractory Depression."
2. "Trends in the Treatment of Major Depressive Disorder and Generalized Anxiety Disorder."
3. "Mood And Social Anxiety Disorders: Long-Term Management and Treatment Strategies."
4. "Diagnosis and Treatment of Depression and Co-Morbid Anxiety Disorders."

Grand Rounds and other forums, Melbourne, Victoria; Sydney, New South Wales; and Brisbane, Queensland. February 4-7, 2002:

5. "The Long-Term Treatment of Depression and Generalized Anxiety Disorders."
6. "The Diagnosis and Treatment of Depression and Co-Morbid Anxiety Disorders."
7. "New Treatment Strategies in the Management Of Depression."
8. "The Diagnosis and Treatment of Chronic Major Depression."
9. "The Treatment of Depression in the New Millennium."

Global Neuroscience Summit, Paris, France. March 8-9, 2002:

10. "Clinical Management of Patients Failing to Respond to Monotherapy and Patients with Treatment-Refractory Depression."
11. "Trends in the Treatment of Major Depressive Disorder and Generalized Anxiety Disorder"
12. "Mood and Social Anxiety Disorders: Long-Term Management and Treatment Strategies"
13. "Rationale and Options for Long-Term Treatment of Depression," Depression: Scientific Experts Meeting IV, Cannes, France. April 5, 2002.

2<sup>nd</sup> Worldwide Neuroscience Consultants Forum, Lisbon, Portugal:

14. "Mood and Anxiety Disorders: Long-Term Management and Treatment Strategies," Workshop Leader. April 28, 2002.
15. "Re-Evaluating Treatment Outcomes: Defining Meaningful Improvement for Patients," Chair, Plenary Session. April 29, 2002.

**Other Presentations**

1. "The Concept and Implementation of Methodology to Study Remission in Anxiety and Depressive Disorders," Remission Across Depression and Anxiety Meeting, Vail, Colorado. February 26, 2002.
2. "Acute, Continuation, and Long-term Treatment for Depression: Do all medications have similar efficacy," Chestnut Hill, Massachusetts. September 25, 2002.

**2003:**

**National Conferences and Grand Rounds**

1. "Course of Bipolar Disorder across the Lifespan," Bipolar Care OPTIONS National Faculty Meeting, New York, New York. February 12, 2003; Regional Meeting presentation, Boston, Massachusetts. May 10, 2003.
2. "Striving to Heal the Mind: The Challenge of PTSD," Chair, Symposium, 156<sup>th</sup> Annual Meeting of the American Psychiatric Association, San Francisco, California. May 21, 2003.
3. "The Long-Term Treatment of Chronic and Major Depression," Grand Rounds, Department of Psychiatry and Behavioral Sciences, Stanford University, Stanford, California. November 6, 2003.

**Other Presentations**

1. "Remission versus Response: The New Gold Standard of Antidepressant Care," Pharmacologic Treatments of Major Depression: Are Two Mechanisms Really Better Than One? (Roundtable), New York, New York. February 10, 2003.
2. "How Do Antidepressants Work?" New Generation of Antidepressants: Truly Better or Much Ado about Nothing? (Duke University Medical Center's Psychiatry & Behavioral Sciences Program Series), Philadelphia, Pennsylvania; New York, New York; and Boston, Massachusetts. February 14, 15, & 16, 2003.
3. "Clinical Management of Patients Failing to Respond to Monotherapy and Patients with Treatment-Refractory Depression," (roundtable). Emory University, Atlanta, Georgia. September 28, 2003.

**2004:****National Conferences and Grand Rounds**

1. "The Long-Term Treatment of Chronic and Major Depression," Grand Rounds (acceptance speech by Dr. Keller as the recipient of the Edward A. Strecker, MD, award), Department of Psychiatry, University of Pennsylvania, Philadelphia, Pennsylvania. January 8, 2004.
2. "Course and Outcome of GAD, Panic Disorder with and without Agoraphobia, and Social Phobia," Second Annual Psychiatric Annals Symposium, New York, New York. March 26, 2004.
3. "The Long-Term Treatment of Recurrent and Chronic Major Depression in 2004: Where Are We and Where Are We Going?" Future Leaders in Psychiatry Symposium, Emory University, West Palm Beach, Florida. April 16, 2004.
4. "The Many Faces of Anxiety: Origins, Pathogenesis, and Management," Chair, Symposium at the 157<sup>th</sup> Annual Meeting of the American Psychiatric Association, New York, New York. May 2, 2004.
5. "Treatment-Resistant Depression Registry," Symposium on Treatment-Resistant Depression, 157<sup>th</sup> Annual Meeting of the American Psychiatric Association, New York, New York. May 5, 2004.
6. "Treating Anxiety and Depression: A Look to Utilizing Antidepressants," American Academy of Family Physicians Meeting, Orlando, Florida. October 13, 2004.

**International Conferences and Meetings**

1. "The Long-Term Treatment of Chronic Major Depression in 2004: Where Are We and Where Are We Going?" U.S.-Cuba Neuroscience Summit, Havana, Cuba. January 17, 2004.
2. "Beyond Depression and Anxiety: Understanding Treatment Myths and Facts," Chair, Satellite Symposium at the 17<sup>th</sup> ECNP Meeting, Stockholm, Sweden. October 9, 2004.
3. "SSRIs and SNRIs: Perceptions, Facts, and Clinical Outcomes in Unipolar Major Depression," 17<sup>th</sup> ECNP Meeting, Stockholm, Sweden. October 9, 2004.

**Other Presentations**

1. "Advances in the Long-Term Treatment of Recurrent and Chronic Depression," Live CME webcast (accredited by Emory University School of Medicine), Washington, DC. September 13, 2004.
2. "The Long-Term Course and Treatment of Anxiety Disorders: Current Knowledge and Future Directions," Innovations in Mental Health Symposium, Skyland Trail, Atlanta, Georgia. November 1, 2004.

**2005:****National Conferences and Grand Rounds**

1. "The Long-Term Treatment of Recurrent and Chronic Major Depression in 2005: Where Are We and Where Are We Going?" Future Leaders in Psychiatry Symposium, Emory University, West Palm Beach, Florida. April 16, 2005.
2. "Diagnosis, Long-Term Course, and Treatment of GAD: Current Knowledge and Future Directions," Grand Rounds, Department of Psychiatry and Behavioral Sciences, Stanford University, Stanford, California. April 21, 2005.
3. "Comorbid Depression and Anxiety: When to Start and Continue with Psychotherapy and Pharmacotherapy," as part of symposium "The Impact of Depression and Anxiety on Wellbeing across the Lifecycle," at The 158<sup>th</sup> Annual Meeting of The American Psychiatric Association, Atlanta, Georgia. May 21, 2005.
4. "Current and Future Treatments of Major Depressive Disorder and Anxiety Disorders," as part of and Chair of symposium "Untangling Depression and Anxiety: A Challenge for Scientists and Clinicians," at The 158<sup>th</sup> Annual Meeting of The American Psychiatric Association, Atlanta, Georgia. May 22, 2005.
5. "Suicide in College Students: Myths, Facts and a Call to Action," (acceptance speech by Dr. Keller as the recipient of the "Voice of Mental Health Award" from the JED Foundation), 2005 JED Foundation Annual Award Ceremony, Carnegie Hall, New York, NY. June 8, 2005.

**2006:****National Conferences and Grand Rounds**

1. "The Long-Term Treatment of Recurrent and Chronic Major Depression: New Paths and Future Directions" Future Leaders in Psychiatry Symposium, West Palm Beach, Florida. May 6, 2006.
2. "Insomnia: Symptom, Syndrome or Disorder," as part of symposium "Insomnia from the Inside-Out (From Neuroscience to Clinical Experience to Public Policy)," at The 159<sup>th</sup> Annual Meeting of The American Psychiatric Association, Toronto, Ontario, Canada. May 21, 2006.
3. "The Long-Term Treatment of Recurrent Major Depression: New Paths and Future Directions," as part of and Chair of symposium "The Long-Term Clinical Course and Treatment of Recurrent Major Depression in 2006: New Paths and Future Directions," at The 159<sup>th</sup> Annual Meeting of The American Psychiatric Association, Toronto, Ontario, Canada. May 21, 2006.
4. "An Overview of Depression Registries," as part of symposium "The Past, Present, and Future Therapies for Treatment-Resistant Depression," at the 29<sup>th</sup> CINP Meeting, Chicago, Illinois. July 9, 2006.



**2007:**

1. "Preventing Recurrent Depression: Long-Term Treatment of Major Depressive Disorder," <http://www.medfair.com>. Internet CME Activity, launch date: February 1, 2007. Blier P, Keller MB, Pollack MH, Thase ME, Zajecka JM, Dunner DL. J Clin Psychiatry. 2007 Mar;68(3):e06.
2. "The Long-Term Treatment of Recurrent and Chronic Depression in 2007 with Pharmacotherapy, Psychotherapy and the Combination: Different Studies with Different Outcomes- What's The Clinician To Do?" Grand Rounds, Department of Psychiatry and Behavioral Sciences, Northwestern University, Feinberg School of Medicine, Chicago, IL. April 18, 2007.
3. "Pharmacological Management of Depression in the Post-Star\*D Era." American Conference of Psychiatric Disorders, New York, NY. September 7, 2007.

**GRANT AWARDS: COMPLETED RESEARCH PROJECTS**

<b>FUNDING AGENCY</b>	<b>TITLE OF GRANT</b>	<b>DATES</b>	<b>TOTAL DIRECT COSTS</b>	<b>DR. KELLER'S ROLE</b>
1) NIMH	Children at Risk for Affective Disorders	1980-1985	\$522,033	Co-PI
2) NIMH	Lithium Levels and Neuroleptics in Bipolar Patients	1982-1989	\$1,377,664	Co-PI
3) NIMH	A Follow-up Study of Children with Affective Disorders	1987-1992	\$741,471	PI
4) NIMH	A Controlled Family Study of Attention Deficit Disorder	1988-1991	\$709,448	Co-PI
5) NIMH	APA Field Trial on Major Depression, Dysthymia and Minor Depression	1990-1993	\$100,000	PI and Chair for 5 sites
6) NIMH	Family Treatment of Bipolar Disorder	1992-1998	\$769,209	Consultant
7) NIMH	Lithium Prophylaxis in Adolescents with Bipolar Illness	1992-2002	\$1,888,797 Brown University site; Total funding approx. \$5,500,000	PI and Member of Steering Committee for 3-site Study
8) NIMH #T32 MH19987	Research Training in Combined Treatment Modalities	1997-2002	\$1,126,570	Co-PI; M. Tracie Shea, PhD
9) Wm. T. Grant Foundation, Psychopathology	Psychopathology, Adaptation and Coping in Children at Risk for Affective Disorders	1981-1986	\$268,000	Co-PI
10) MacArthur Foundation	Network I Core Laboratory for Longitudinal Studies	1989-1992	\$120,477	PI
11) E. Merck Industries, Inc. Pharma Division	A Phase III, Randomized Double Blind, Dose Finding Study of Roxindole vs. Placebo in Depressed Outpatients	1993-1994	\$229,380	PI
12) The Upjohn Company	Platelet MAO Levels in Affective Disorders	1980-1984	\$100,000	PI
13) The Upjohn Company	Influence of Depression on Treating Panic Disorder	1986-1992	\$508,000	PI
14) The Upjohn Company	Detection of Anxiety and Depression among Patients in Family Medicine Practices	1991-2000	\$203,597 Brown University site	PI

**GRANT AWARDS: COMPLETED RESEARCH PROJECTS (CONT'D)**

<b>FUNDING AGENCY</b>	<b>TITLE OF GRANT</b>	<b>DATES</b>	<b>TOTAL DIRECT COSTS</b>	<b>DR. KELLER'S ROLE</b>
15) The Upjohn Company	Harvard Brown Anxiety Research Program	1994-1995	\$2,382,442	PI and Chair of 12-Medical Center Study
16) Hoffman LaRoche	Randomized Clinical Trial to Establish the Efficacy of Treating Social Phobia	1992-1994	\$225,000	Co-PI
17) Pfizer, Inc.	Acute and Continuation Randomized Clinical Trials to Establish the Efficacy of Treating Dysthymia	1992-1995	\$150,000	Co-PI
18) Pfizer, Inc.	Randomized Clinical Trials to Establish the Efficacy of Treating Generalized Anxiety Disorder	1992-1993	\$56,000	Co-PI
19) Pfizer, Inc.	Safety and Efficacy of 3 Doses of Oral CP-88,059-1 in Acute Schizophrenia	1992-1993	\$79,695	Co-PI
20) Pfizer, Inc.	Acute, Continuation, and Maintenance Crossover Randomized Clinical Trials to Establish the Efficacy of Treating Double Depression	1992-1998	\$1,060,000; Brown University site; Total funding approx. \$13,000,000	PI and Chair for 12-Medical Center Study
21) Pfizer, Inc.	Acute, Continuation, and Maintenance Crossover Randomized Clinical Trials to Establish the Efficacy of Treating Chronic Major Depression	1992-1998	\$620,000 Brown University site; Total funding approx. \$7,000,000	PI and Chair for 12-Medical Center Study
22) Pfizer, Inc.	Double-Blind Parallel Comparison of Sertraline and Placebo in Patients with a DSM-IV Diagnosis of Alcohol Dependence and Co-Morbid Depression	1996-1999	\$236,000 Brown University site; Total funding approx. \$5,000,000 (administered by Roger Williams Med Ctr/Butler Hospital)	PI and Chair for 12-Medical Center Study
23) Pfizer, Inc.	An 8-Week Parallel-Group, Double-Blind, Placebo Controlled Study of Sertraline in the Treatment of Elderly Outpatients with Major Depression	1997-1998	\$71,250 Brown University site; (administered by Butler Hospital)	PI
24) Pfizer, Inc.	An 8-Week, Multicenter, Parallel-Group, Double-Blind, Placebo Controlled Study of St. John's Wort in Outpatients with DSM-IV Major Depression	1998-2001	\$200,000 Brown University site; (administered by Lifespan at RI Hospital)	PI and Co-Chair, Steering Committee for 10-Medical Center Study



**GRANT AWARDS: COMPLETED RESEARCH PROJECTS (CONT'D)**

<b>FUNDING AGENCY</b>	<b>TITLE OF GRANT</b>	<b>DATES</b>	<b>TOTAL DIRECT COSTS</b>	<b>DR. KELLER'S ROLE</b>
25) SmithKline Beecham	A Multi-center, Double-blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression	1993-1998	Approx. \$800,000 Brown University site; Total funding approx. \$5,000,000	PI and Coordinating PI of 12-Medical Center Study
26) SmithKline Beecham	Prospective Naturalistic Follow-up Study of Unipolar Depression in Adolescents	1997-1999	\$20,000 Brown University site; Total funding approx. \$500,000	PI and Chair for 12-Medical Center Study
27) Bristol-Myers Squibb	Acute, Continuation, Crossover and Maintenance Study of the Treatment of Chronic Major Depression with Cognitive Behavior Therapy alone, Nefazodone Alone, and in Combination	1995-2001	Approx. \$960,000 Brown University site; Total funding approx. \$25,000,000 (administered by RI Hospital)	PI and Chair for 12-Medical Center Study
28) Bristol-Myers Squibb	A Multisite Study of a Slow Release "Patch" of Buspirone to Treat Children and Adolescents with Attention Deficit Disorder	1997-1998	\$100,000 Brown University site (administered by RI Hospital)	PI
29) Organon	Placebo-Controlled Study of Relapse Prevention by Long-Term Treatment with Remeron in Outpatients with Recurrent Major Depressive Episode	1997-1999	\$360,000 Brown University site (administered by RI Hospital)	PI and Co-Chair for 12-Medical Center Study
30) Forest Laboratories	An Open-Label Evaluation of the Efficacy, Safety and Dosing of Citalopram in Outpatients with Depression	1998-1999	\$40,040 Brown University site (administered by Butler Hospital)	PI
31) Forest Laboratories	A Randomized, Double-Blind, Placebo-Controlled Trial of Citalopram in Depressed Patients at Least 75 Years of Age	1998-2001	\$200,000 Brown University site; (administered by Butler Hospital)	PI
32) Wyeth-Ayerst	Double-blind, Placebo-Controlled Study of Treatment of Depression in Adolescents	1998-2000	\$196,000 Brown University site	PI
33) Wyeth	An Open-Label Randomized Assessment of the Efficacy and Tolerability of Venlafaxine ER in Selective Serotonin Reuptake Inhibitor (SSRI)-Failure Patients with Major Depression	1999	\$81,180 Brown University site (administered at RIH)	Investigator with 3-site study

**GRANT AWARDS: CURRENT RESEARCH PROJECTS**

<b>FUNDING AGENCY</b>	<b>TITLE OF GRANT</b>	<b>DATES</b>	<b>TOTAL DIRECT COSTS</b>	<b>DR. KELLER'S ROLE</b>
1) NIMH #5R01MH25478-28	Collaborative Depression Study on the Psychobiology of Depression	1976-2009	\$7,169,378 Mass General Hospital Brown Univ site; Total funding approx. \$32,000,000	PI and Chair for 5-Medical Center Study
2) NIMH #2R01MH51415	The Harvard/Brown Anxiety Research Project (HARP)	1994-2008	\$4,205,195 Brown	PI
3) NIMH #R01MH50837	Collaborative Longitudinal Study of Personality Disorders	1996-2009	\$2,296,205 Brown University site; Total funding approx. \$7,000,000	Co-PI; Member of Steering Committee of 4-Site Study
4) NIMH #R01MH59691	Course and Outcome for Adolescents with Bipolar Illness (COBY)	2000-2011	\$3,384,131 Brown; University (with Bradley Hospital subcontract) Total funding approx. \$11,000,000	PI and Member of Steering Committee of 3-site Study
5) NIMH #U10MH62014	Treatment of SSRI-Resistant Depression in Adolescents (TORDIA)	2000-2007	\$1,007,450 Brown University site; (administered at Brown with RI and Bradley Hospitals subcontract; Total funding approx. \$12,600,000	PI and member of Steering Committee for 6-site Study
6) NIMH #1U10 MH61590-01A2	CBASP for Treatment of Chronic Depression (also known as REVAMP: Research Evaluating the Value of Augmenting Medication with Psychotherapy	2002-2009	\$1,009,244 Brown University site; Total funding over \$9,000,000 (approx.)	PI; Member of Steering Committee
7) Pfizer, Inc.	The Primary Care Anxiety Disorders Program	1997-	\$6,952,763 Brown University site	PI
8) Department of Defense	Establishing the Parameters of Virtual Reality Environments in the Treatment of PTSD (VR-PTSD)	2007-2009	\$356,000	PI

**UNIVERSITY AND HOSPITAL TEACHING ROLES:****Massachusetts General Hospital (Harvard Medical School):**Developed and taught:

- 1975-1986 Seminar on psychopathology for residents in psychiatry, Massachusetts General Hospital (MGH)
- 1977-1979 Course on psychopathology, Harvard School of Public Health
- 1978-1986 Introduction to Psychotherapy seminar for residents and psychology interns, MGH
- 1980-1986 Clinical Program for Harvard Medical School Students in outpatient psychiatry
- 1985-1990 Course on affective disorders for residents in psychiatry, MGH
- 1986-1990 Seminar on research methodology for MGH psychiatry residents, psychology trainees, and faculty

Other teaching roles:

- 1976-1986 Chair, weekly clinical evaluation conference for residents in psychiatry, MGH
- 1976-1986 Co-chair, weekly case conference for residents in psychiatry, MGH
- 1976-1989 Clinical Supervisor of Psychotherapy, MGH
- 1976-1989 Lecturer in Continuing Medical Education courses, MGH
- 1977-1980 Clinical Supervisor of Psychotherapy, Boston Institute of Psychotherapy
- 1985-1990 Course Director, MGH Continuing Medical Education course on Affective Disorders (given bi-annually)

Principal Clinical and Hospital Service Responsibilities, MGH:

- 1976-1986 Director, General Psychiatry Practice (Ambulatory Psychiatric Services)
- 1986-1990 Director of Outpatient Research, Department of Psychiatry

**Brown University School of Medicine****(Department of Psychiatry & Human Behavior):**

- 1990-1995 Seminar on research for adult psychiatry residents
- 1990-1996 Director, Post-Graduate Research Fellowship Program
- 1993- Chairman's Rounds (weekly rounds with residents in general psychiatry; quarterly rounds with child & adolescent psychiatry and triple-board residents [combined pediatrics, psychiatry, and child & adolescent psychiatry])
- 1995- Research Rounds (monthly with full-time faculty at Lifespan and Care New England/VA Medical Center)
- 2001- Journal Club (quarterly with residents in general psychiatry)